Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA
CIVIL DIVISION

UNITED STATES OF AMERICA, *ex rel.*
BEN R. STOKES,
Seafirst Fifth Avenue Plaza
800 Fifth Street, Suite 4100
Seattle WA 98104

CASE NO.

Relator,

vs.

TO BE FILED UNDER SEAL

BOSTON SCIENTIFIC,
One Boston Scientific Place
Natick, MA 01760-1537

MEDTRONIC, INC.
710 Medtronic Parkway
Minneapolis, MN 55432-5604

ST. JUDE MEDICAL, INC.
1 St. Jude Medical Drive
St. Paul MN
55117

DO NOT FILE ON PACER
DO NOT PLACE IN PRESS BOX

Defendants.

QUI TAM RELATOR'S COMPLAINT UNDER 31 U.S.C. §3729, FEDERAL FALSE CLAIMS ACT

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Introduction

Relator Ben R. Stokes, by and through his counsel, states his Complaint to the Court as follows:

1. Mr. Stokes is the former Sr. Manager of Healthcare Economics for Defendant Medtronic, Inc. Mr. Stokes held this position until June of 2009 when he voluntarily resigned.

2. The Defendants to this Complaint are the leading pacemaker manufacturers which collectively represent over 90 percent of the pacemaker market in the United States.
3. The Defendants manufacture, market, and program pacemakers. Defendants benefit financially from maximizing the number of procedures to implant and replace pacemaker generators (the batteries) in Medicare patients.
4. Through his employment and work experience, Mr. Stokes discovered that agents of pacemaker manufacturers have caused premature depletion of pacemaker batteries, causing Medicare patients to undergo unnecessary surgical procedures to replace the pacemakers and causing substantial expense to the Medicare Program.
5. Chemical energy in the generator is consumed by use. When the generator's voltage output falls to a level in which cardiac stimulation can no longer be maintained, the generator must be replaced.
6. The pacemaker is hermetically sealed and the majority of it is actually the lithium-iodide battery or generator. Replacing the generator means replacing the pacemaker itself. The patient must undergo surgery in which the leads or wires attached to the heart are left in place and reconnected to the new pacemaker.

7. The longevity of pacemaker generators is dependent on three factors: (1) the individual patient's pacing dependency, (2) the design and integrity of the pacing system components (batteries and leads), and (3) the programmed settings of the device.

8. After implantation, the programmed settings are customarily set by allied professionals employed by the Defendant device manufacturers. These allied professionals program the devices in the follow-up period after implantation. The sales representatives or allied professionals employed by the Defendants are the direct beneficiaries of each pacemaker sold and each procedure to replace the pacemaker due to generator depletion.

9. Each time Defendants' respective sales agents program a pacemaker, a record is created and transmitted to their employers which are Defendants in this action. For each pacemaker programmed by their agents, Defendants have a written history of the voltage output settings on that pacemaker.

10. Among the variables which affect generator longevity, output settings are the only variable which can be manipulated. If a pacemaker is programmed incorrectly or left at high output settings, premature generator depletion will occur.

11. The respective Defendants closely track the incidence of generator replacement procedures associated with each employed sales representative. The respective

Defendants track the incidence of generator replacements at each hospital where their allied professionals are marketing and programming pacemakers.

12. The Defendants track and know the numbers of generator replacement procedures each month and each quarter. They know the identity of each of their respective sales representatives or allied professionals involved in the programming of each particular pacemaker with a depleted generator.

13. For each of their manufactured pacemakers, the respective Defendants have written records of the programmed settings. Each time Defendants' agents set the output voltage on a pacemaker, a record is created and sent to the respective Defendant manufacturers. The programmed settings are also stored on the computer hard drive within the pacemaker.

14. Defendants closely monitor and track their sales representatives by numbers of generator replacement procedures each quarter of each fiscal year. They closely monitor and track revenues associated with each generator replacement for pacemakers programmed by each sales representative at every hospital in the United States.

15. The Defendants have extensive programs in place to train their employed allied professionals in programming pacemaker settings. Defendants train their employees with detailed instructions and data addressing the longevity of pacemaker generators at different programmed settings. The Defendants and

their respective employees know the importance of reprogramming pacemakers after implantation to maximize generator longevity. They understand the economic incentives to permit or cause premature generator depletions in their pacemaker products.[1]

16. For example, the Medtronic EnPulse DR series, including models E1DRO1, E1DR03, and E1DR06, have a generator longevity range of 4.4 years at the

[1] Numerous textbooks, national consensus guidelines, and international consensus guidelines have recognized the importance of reprogramming pacemakers after the sub-acute period of implantation. In 2002, the American College of Cardiology, American Heart Association, and the North American Society of Pacing and Electrophysiology published their "Guideline Update for Implantation of Cardiac Pacemakers, and Antiarrhythmia Devices." ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices, A Report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines, at *www.acc.org/clinical/guidelines/pacemaker/pacemakerpdf.*

The ACC/AHA/NASPE Consensus Guidelines stated in pertinent part, "Programming undertaken at implantation should be reviewed before discharge and changed accordingly at subsequent follow-up visits as indicated by interrogation, testing and patient needs." "With careful attention to programming pacing amplitude, pulse width, and diagnostic functions, battery life can be enhanced significantly without compromising patient safety." *Id.* at p. 22.

In 2003, the North American Society of Pacing and Electrophysiology published Standards of Professional Practice for the Allied Professional in Pacing and Electrophysiology. PACE, Volume 26, pp. 127-131 (January 2003). The Standards of Professional Practice were "developed to articulate the scientific foundation, clinical skills, and technical knowledge requisite to provide and facilitate the provision of safe quality patient care." Under the Section "Device Follow-Up," the allied professional is required to "program device parameters, controlling for optimal safety, longevity, and therapeutic needs of the patient." *Id.* at p. 130.

high 5.0 volt setting to 7.5 years at the low 2.5 volt setting. The Kappa 700 DR, including models KDR701, KDR703, and KDR706, have a generator longevity range of 3.0 years at the high 5.0 volt setting to 5.5 years at the low 2.5 volt setting.

17. Each pacemaker generator manufactured by each Defendant has a wide range of potential longevity depending on the output settings. The respective Defendants and their agents know the exact longevity ranges and associated output settings for each pacemaker generator and each pacemaker model.

Introduction to Surge in Generator Replacement Rates for Medicare Patients in Last Six Years

18. Mr. Stokes' investigation and analyses confirm that generator replacement procedures represented approximately 13 percent of total pacemaker cases among Medicare patients in 2004. Total pacemaker cases include both new pacemaker implant procedures and pacemaker generator replacement procedures.

19. That rate of 13 percent had been stable dating back to 1993. For 12 years prior to 2005, generator replacement rates in the Medicare population had a direct linear relationship with total pacemaker cases. That linear relationship was a stable flat line at approximately 13 percent of total pacemaker cases.

20. Yet in the subsequent four years of 2005, 2006, 2007, and 2008, Mr. Stokes' investigation and analyses reveal that gemerator replacement procedures in Medicare patients escalated from 13 percent of total pacemaker cases in 2004 to approximately 28 percent of total pacemaker cases in 2007 and 2008.
21. In 2002, the Medicare Program paid for 19,751 pacemaker generator replacement procedures.
22. In 2004, the Medicare Program paid for 26,942 pacemaker generator replacement procedures.
23. In 2007, the Medicare Program paid for 44,621 generator replacement procedures.
24. In 2008, the Medicare Program paid for 43,547 pacemaker generator replacement procedures.
25. Within the five-year period of 2002-2007, the number of pacemaker generator replacement procedures billed to Medicare more than doubled from 19,751 to 44,621 procedures. This escalation occurred in a time period of stable and improving generator technology and in the same time period that the Defendants touted the longevity of their pacemaker products and reported minimal generator replacement procedures needed for their products.
26. If the historical stable rate of generator replacement procedures from 1993-2004 had continued through 2008, then the Medicare Program would have paid

for approximately 65,031 less procedures to replace pacemaker generator at a cost of approximately $10,000 per procedure. If the historical 13-year constant rate of generator replacement procedures from 1993-2004 had continued through 2008, then between 2005 and 2008, approximately 65,031 Medicare patients would not have undergone an invasive surgical procedure to replace a pacemaker generator.

27. The escalation of generator replacement procedures is alarming. Of greater concern is that **even after considering the national growth in the percent of generator replacement procedures and the major jump nationally in numbers of generator replacement procedures, there are multiple geographic clusters of facilities with generator replacement rates in excess of two standard deviations beyond national norms.** The results of Mr. Stokes' analyses are statistically significant at a level of $p<.005$. There is less than ½ of 1 percent chance that the results were due to randomness. Multiple cluster locations are discussed below.

28. With respect to the eighteen clusters which represent geographic locations of generator replacement rates repeatedly in excess of one or two standard deviations for multiple years within the time period of 2004-2008, damages to the Medicare Program exceed 80 million dollars.

29. The Defendants' agents market, sell, and program pacemakers within each of the geographic clusters discussed below.

30. The Defendants have concealed the true incidence of premature generator depletion among their pacemaker products, their agents have caused or contributed to such depletions, and they have profited at the expense of the Medicare Program and to the detriment of vulnerable elderly Medicare patients undergoing unnecessary surgical procedures to replace pacemaker generators. [2]

Jurisdiction, Venue, and Parties

31. This is an action to recover damages and civil penalties on behalf of the United States of America arising out of the false claims presented for payment under the Federal Medicare Program. This action arises under the provisions of Title 31 U.S.C. §3729, *et seq*, popularly known as the False Claims Act, which

[2] Pacemaker generators have a finite life; however, the generator lifespan varies over a broad range depending upon voltage output settings. Generator replacements procedures are not inevitable for all patients, particularly among Medicare patients whose life expectancy is commonly shorter than generator longevity. In a study analyzing National Inpatient Sample data over the time period of 1993-2006, the "mean age of primary and replacement [pacemaker] patients was 75.5 (+- 12.1 years) and 73.6 (+- 16.0)." Kurtz S Ochoa J, Shkoinikov Y, "*Implantation Trends and Patient Profiles for Pacemakers and Implantable Cardioverter Defibrillators in the United States: 1993-2006*," 33(6) PACING AND CLINICAL ELECTROPHYSIOLOGY 705-711, 708 (2010). According to Defendants' own Product Performance Reports, the vast majority of pacemakers are taken out of service for reasons other than generator replacements. The most common reason is patient mortality.

provides that the United States District Courts shall have exclusive jurisdiction of actions brought under the Act.

32. Section 3732(a) of the Act provides that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred."

33. An action for violation of the False Claims Act may be brought by the Attorney General under 31 U.S.C. §3730(a) or by private persons under the qui tam provisions of 31 U.S.C. §3730(b).

34. The Court has subject matter jurisdiction over this action under 28 U.S.C. §§1331 and 1345. The Court may exercise personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a). All three Defendants transact business in this District. All of the Defendants market, sell, and program pacemakers for Medicare patients in this District. Moreover, the Defendants' agents schemes to program pacemakers at excessive output levels have caused false claims against national federal health care programs which programs are funded and managed from federal agencies within the District of Columbia.

35. Further, the consolidation of all Defendants in this single action is proper because of common questions of law and fact.

36. There has been no prior public disclosure of "substantially the same allegations or transactions as alleged in [this] action…in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party" or "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; …or from the news media." 31 U.S.C. 3730 § (4)(A).

37. In the 2010 Amendment to 31 U.S.C. 3730 § (4)(A), the deletion of the word "jurisdiction" and the addition of the language "unless opposed by the Government" changed the public disclosure defense from a jurisdictional bar to a defense that automatically fails if opposed by the government.

38. Mr. Stokes did not happen upon any allegations of fraud against any defendant in any publicly disclosed documents. There is no publicly disclosed document which explicitly reveals any of the false claims against any of the Defendants at issue in this action.

39. The allegations or transactions of false claims as alleged in this action have **not** been publicly disclosed in the enumerated sources of 31 U.S.C. 3730 § (4)(A) or any other source.

40. Rather, as discussed in detail further below, Mr. Stokes' employment experience working inside the industry, his direct personal knowledge gained through his position at Medtronic, his personal communications with numerous

facilities experiencing excessive generator replacement rates, his personal review of generator replacement data available as part of his former position at Medtronic, and his extensive investigation and independent analyses detected and exposed the schemes to cause generator depletion and false claims against the Medicare Program.

41. Moreover, through his personal knowledge, experience, and investigation, Mr. Stokes has independent knowledge of the information underlying the allegations of false claims in this case. Although there has been no public disclosure as defined under the False Claims Act and therefore no requirement for Mr. Stokes to qualify as an "original source," Mr. Stokes would qualify as an "original source" under amended 31 U.S.C. § 3730 (4)(B). He "has knowledge that is independent of and materially adds to" any alleged "publicly disclosed allegations or transactions" and he has "voluntarily provided the information to the Government before filing an action under this section. *Id.*

42. Without Mr. Stokes' knowledge and extensive efforts, the investigation into the issues raised in this Complaint would not exist.

43. Mr. Stokes has served a copy of the Complaint and written disclosure of substantially all the material evidence and information in his possession upon the United States Department of Justice. Mr. Stokes also provided detailed notice to the United States Department of Justice weeks prior to filing the

Complaint, including delivery of the draft Complaint and his Disclosure with Exhibits to the United States Attorney General and the United States Attorney for the District of Columbia before filing this action under seal.

Introduction to Pacemakers and Pacemaker Programming

44. A pacemaker is a small, generator-powered medical device designed to electrically stimulate the heart muscle in an effort to restore a normal heart rhythm. A pacemaker system consists of two main parts: the pulse generator and pacing leads. The pulse generator houses the generator and electronic circuits (like a small computer). These circuits contain sensors and timers that identify and regulate how often the pacemaker must send impulses to stimulate the heart. The pulse generator is small, measuring approximately 2" x 2" x 1/4" (45mm x 45mm x 6mm) and weighing less than 2 ounces (20-30g). The pacing leads are flexible, insulated wires that connect to the pulse generator and carry the electronic impulse to the heart. The leads also carry signals back from the heart to the pulse generator allowing the pulse generator to sense the heart's natural electrical activity. By sensing the patient's natural rhythm, the pacemaker will only pace the heart when necessary.

45. Pacemakers may be single or dual chamber. Single chamber pacemakers use a single lead attached to either the heart's upper chamber (atrium) or lower

chamber (ventricle). Dual chamber pacemakers use two leads, one attached to the atrium, the other to the ventricle. Leads can be attached either to the heart's inside surface (endocardium) or outside surface (epicardium).

46. Leads attached to the endocardium can be surgically placed through a vein that communicates with the heart. The leads are positioned within the heart with the help of a type of X-ray called fluoroscopy. The vast majority of US pacemakers are placed in this manner.

47. Leads attached to the epicardium require surgical exposure of the heart by using an incision through the chest wall. The pulse generator is positioned under the skin (and sometimes also under the muscle) in the upper chest near the collar bone or in the abdominal area depending on the age and size of the patient.

48. The device manufacturer representative can later communicate with and reprogram the pulse generator with a special pacemaker programmer.

49. Certain Medicare patients may benefit from pacemaker implantation, including patients with abnormally slow heart rates, patients who pass out, patients on medications that slow the natural heart rate, patients with heart valves that leak (regurgitation), patients with an abnormally thick heart (hypertrophic cardiomyopathy), and patients with poor heart function.

Artificial pacing helps to restore a normal heart rhythm, thereby improving the heart's ability to circulate blood through the body.

50. The most common reason for a repeat operation is the need to replace the pulse generator because of energy depletion. How long the pacemaker's generator will last depends on the pacemaker's programmed settings as well as how frequently the pacemaker is used. Replacement of the pulse generator entails making an incision over the old pulse generator, disconnecting it from the existing pacing leads, and replacing it with a new pulse generator.

51. At the time of implantation, the physician attempts to place the wires which carry energy from the generator to the heart (aka “leads”) into an area of the heart that is most receptive to electrical stimulation. The physician will slowly decrease the amount of energy being delivered through the leads until the energy fails to initiate a heartbeat, otherwise known as “loss of capture.” The physician will then increase the energy to a level somewhat higher than the lowest needed to initiate a heartbeat, so that a reasonable safety margin exists between the lowest energy needed and the actual energy that the device will be set to deliver. This is done to ensure that the heart will have the highest probability of long-term receptivity to the pacemaker’s electrical stimulation, and that the least amount of energy will be required to stimulate each heartbeat. This final setting is known as the pacing threshold.

52. Once this area is found, and the pacing threshold has been identified, the lead is fixated to the heart wall. This fixation causes some temporary inflammation at the fixation site, which makes it less receptive to electrical impulses until the inflammation has been eliminated. For this reason, device representatives commonly set the generator output to at least twice the pacing threshold for the initial implant settings. This physiologic response is also the reason that most leads today have steroid tips, which are intended to minimize the inflammatory response.

53. After implantation, pacemakers require monitoring to ensure proper function and programming. The first device evaluation typically occurs within 4 months after implantation and continues throughout the life of the patient. It is at this first device monitoring appointment that the settings should be restored to the pacing threshold rates, so that the patient receives the nominal amount of energy needed to initiate a heartbeat and/or receive optimal therapy.

54. At each subsequent visit during the life of the device, the settings should be reviewed and optimized so that the patient receives the nominal amount of energy needed to initiate a heartbeat.

55. There are multiple opportunities throughout the life of the device to achieve optimal settings concerning programming and energy output. The optimal settings are the nominal amount of energy needed to initiate a heartbeat and/or

deliver the required therapy. This is well understood by device manufacturer representatives who set the output voltage settings.

56. Unlike most other aspects of patient care in medicine, during implantation and throughout the follow-up care of the patient, representatives of the Defendant device manufacturers have direct contact with patients and typically handle device settings and function (aka "interrogation") and reprogram device settings (aka "reprogramming) through computerized evaluation of the device and radiofrequency communications with the device during follow-up. The "interrogation" and "reprogramming" typically take place in outpatient cardiologist practices or in outpatient hospital "device clinics." In either setting there are manufacturer personnel who are specifically trained to program the device settings, including energy output.

57. The manufacturer-specific nature of programmers typically means that allied professionals employed by the Defendant manufacturers have more knowledge about a particular device and its associated programmer than a physician or nurse.

Introduction to Mr. Stokes' Employment, Experience, and Investigation

58. While touting the longevity of their devices, the reality is that generator replacement procedures have escalated in the last 6 years with clusters of excessive generator replacement procedures in close geographic proximity.

59. In his role as Sr. Manager of Healthcare Economics employed by Defendant Medtronic, Mr. Stokes had the unique opportunity to travel throughout the United States, visiting hospitals and delivering education pertaining to documentation, coding and billing for cardiac devices such as pacemakers and ICDs. During his tenure of employment at Medtronic, he personally visited and worked with over 300 hospitals across 40 states. As he would visit with customers in the various facilities, they would share how their device costs, case mix, payor mix and utilization trends were impacting their overall profitability for these procedures. Because of this experience, he began to be able to recognize metrics that were inconsistent with the "norms" he was learning from the majority of other facilities. One of the metrics that caught his attention early on was the anomalies he would see in device replacement rates among Medtronic customers where Medtronic's employed sales agents worked to program pacemakers.

60. At the same time, he was personally developing the majority of Medtronic's economic tools and resources. Some of these were internal analytic tools designed to educate and equip sales teams regarding various objections they

may receive from customers concerning device features and benefits and their associated costs. Among these various tools that he developed was one that looked at pacemaker longevity and its impact on costs and profitability.

61. Simultaneously, he began to develop a customer-facing, sensitivity tool which allowed Medtronic to estimate a specific facility's profitability on individual procedures by making various revenue and cost driver factors. Part of that development included reviewing MedPAR data to establish base-rate data for certain variables within the model, including national pacemaker implant and replacement rates. As he began to use the tool, he continued to see abnormal spikes in device replacement rates among Medicare patients at various hospitals.

62. Mr. Stokes knew that the principal drivers of device longevity were the patient's own demand for pacing; the quality and integrity of the device components themselves; and the energy settings programmed in the device. From his employment experience in the industry, Mr. Stokes knew that patient pacing demand was stable and normalized on a national level; that pacemaker generators were reasonably stable from a component standpoint; and that generator technology was competitive and stable among the various device companies.

63. He also knew that in addition to the economic incentives for device growth, there was a clinical environment vulnerable to abuse by manufacturers' agents. The fact that device interrogations and reprogramming are customarily performed by the device representatives themselves, without direct physician supervision or review, means that the stakeholder who benefits most from device replacements is typically the same person who controls the programmed settings on the device.

64. In a larger context, the cardiac rhythm device industry was booming at this time. A landmark trial called SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) ushered in a major expansion of implantable cardioverter defibrillator (ICD) indications. This rapid expansion of ICD indications and utilization captured the attention of industry and hospitals. While hospitals were concerned about profitability on these expensive devices, the industry as a whole, and device representatives in particular, were enjoying unprecedented profits and growth projections. Medtronic and others were hiring and expanding. However, the growth that SCD-HeFT promised was not sustained and never fully materialized due to provider concerns about costs and a general lack of awareness about the new indications. On top of that, a series of unprecedented device re-calls began to unfold, seriously eroding the confidence of patients and physicians in device therapy. Suddenly, the income

of device companies fell dramatically, and the sales representative competition at the local level for every device implant heated up. Pacemakers began to be appreciated again as a kind of "stable annuity" against the volatility of the ICD business.

65. Through his position as Sr. Manager of Healthcare Economics for Medtronic's Cardiac Rhythm Disease Management, Mr. Stokes personally and directly saw evidence of excessive spikes in generator replacement rates among some Medtronic customers. In addition to the significant spikes that Mr. Stokes witnessed in generator replacement rates among Medtronic customers where pacemakers were being programmed by Medtronic's employees, Mr. Stokes also received information about a sales agent employed by Boston Scientific who was programming pacemakers at excessive output levels to deplete generator longevity. This sales agent was marketing and programming pacemakers being implanted at two particular hospitals in Texas.

66. Mr. Stokes obtained and analyzed the total pacemaker cases at both of these facilities, including new system pacemaker implants and generator replacement procedures over the five-year period of 2004 to 2008.

67. The patterns at both hospitals indicated the presence of artificial influences on the rates of generator replacement procedures with striking aberrational rates of replacement procedures as compared to national norms.

68. But of greater concern to Mr. Stokes was that as he did his detailed national analyses, there were multiple locations with more striking data, patterns, and indicators of manipulated influences on generator replacement procedures.

69. From his employment experience, Mr. Stokes knew that there were agents of device manufacturers causing premature generator depletions and causing increased surgical procedures to replace depleted generators among Medicare patients. As part of his position as Senior Manager of Healthcare Economics at Medtronic, Mr. Stokes personally saw recurrent evidence of such conduct at locations where he evaluated detailed data on generator replacement rates and new pacemaker implant procedures.

70. To investigate the scope of schemes to deplete generators through high voltage settings, Mr. Stokes undertook extensive analyses of national Medicare pacemaker generator replacement claims data. In performing such analyses, Mr. Stokes used many of the same analytical methods and statistical tools used in his former position at Medtronic to evaluate pacemaker and generator replacement data among Medicare patients.

71. The Centers for Medicare and Medicaid Services (CMS) receives claims data from medical providers treating Medicare patients. The Medicare Provider Analysis and Review (MedPAR) file contains claims data received from medical providers treating in-patients who are Medicare beneficiaries. The

national file consists of approximately 12 million records per year. A separate file is maintained for each federal fiscal year (October 1 – September 30).

72. Within MedPAR, there are millions of codes corresponding to millions of patient admissions for Medicare beneficiaries. To report a particular medical condition or medical procedure, Medicare has established a coding system for hospitals participating in the Medicare program. A particular numeric code signifies a particular medical diagnosis or procedure. For each Medicare claim, there are nine potential fields for diagnostic codes and six potential fields for procedure codes. MedPAR is entirely composed of diagnostic and procedure codes associated with each in-patient admission for each Medicare patient.

73. Mr. Stokes has compiled, organized, and analyzed thousands of data points pertaining to pacemaker generator replacement and new pacemaker procedures at facilities across the United States.

74. Mr. Stokes used the United States Medicare Provider Analysis Report ("MedPAR") and the US Medicare Outpatient Claims Data set for the years 2004, 2005, 2006, 2007, and 2008. The benefits of these datasets include: (a) largest and most current sample size available; (b) least impacted by the variable of state and/or carrier specific coverage determinations; and (c) well-suited for the age demographic meeting pacemaker therapy.

75. With the US Medicare Provider Analysis Report ("MedPar") data for years 2004 thru 2008, Mr. Stokes used the following Medicare Diagnostic Related Groups ("DRG") as query metrics:

- 2004 MedPar Query: DRG 115, DRG 116, and DRG 118
- 2005 MedPar Query: DRG 115, DRG 116, and DRG 118
- 2006 MedPar Query: DRG 551, DRG 552, and DRG 118
- 2007 MedPar Query: DRG 242, DRG 243, DRG 244, DRG 258, and DRG 259
- 2008 MedPar Query: DRG 242, DRG 243, DRG 244, and DRG 259

With US Medicare Outpatient Claims Data ("OP") for years 2004 thru 2008, Mr. Stokes used the following Current Procedural Terminology ("CPT") codes as query metrics:

- OP 2004: CPT 33206, CPT 33207, CPT 33208, CPT 33212, CPT 33213, and CPT 33214
- OP 2005: CPT 33206, CPT 33207, CPT 33208, CPT 33212, CPT 33213, and CPT 33214
- OP 2006: CPT 33206, CPT 33207, CPT 33208, CPT 33212, CPT 33213, and CPT 33214

- OP 2007: CPT 33206, CPT 33207, CPT 33208, CPT 33212, CPT 33213, and CPT 33214
- OP 2008: CPT 33206, CPT 33207, CPT 33208, CPT 33212, CPT 33213, and CPT 33214

76. MedPAR is millions of innocuous numbers or codes. There is no allegation of fraud within MedPAR which is composed entirely of codes as referenced above for example. There is no allegation whatsoever within MedPAR. There is no disclosure of fraudulent transactions within MedPAR itself.

77. The coding numbers within MedPAR are submitted by the hospitals treating Medicare beneficiaries. The coding numbers are not a federal or governmental report or any inquiry by the government. They are simply numerical codes submitted by the hospitals treating Medicare beneficiaries.

78. Accurate coding is critical to the Medicare Program. Coding is used to determine payments under the Medicare Program. In their submissions to Medicare, medical providers have certified the accuracy of the diagnoses and procedures reported to Medicare through the coding system.

79. MedPAR contains records for 100% of Medicare beneficiaries who use hospital inpatient services. The records are stripped of most data elements that will permit identification of beneficiaries. The six position Medicare billing number identifies the hospital.

80. Through Mr. Stokes' extensive analyses of generator replacement rates and total pacemaker cases, 35 hospitals emerged with replacement rates repeatedly in excess of one or two standard deviations beyond the cohort averages for the time period 2004-2008. Each of these 35 facilities is joined by other facilities in close proximity with patterns of excessive generator replacements.

81. In evaluating these facilities with the highest rates of replacement procedures as compared to national norms, eighteen geographic clusters emerged.

82. Mr. Stokes believes that these geographic clusters evidence the leading locations or sales territories of manufacturers' employees setting the pacemakers at excessive levels of voltage output. Each Defendant employs agents who market and program pacemakers within the clustered locations. The clusters mark the territory of multiple facilities with replacement rates repeatedly exceeding one or two standard deviations over cohort averages during the five-year period.

Summary of Mr. Stokes' Investigation and Analyses of Data on Pacemaker Generator Replacement Procedures Among Medicare Patients

83. In Mr. Stokes' analyses of replacement rates at the final cohort of 572 hospitals, geographic clusters as determined by Medicare CBSA codes

emerged with evidence of recurrent replacement rates in excess of two standard deviations beyond cohort averages.

84. The Medicare CBSA or Core-Based Statistical Area is the name used by the Centers for Medicare and Medicaid Services to describe both metropolitan statistical areas (population of 50,000 or more people) and micropolitan statistical areas (population from 10,000 up to 50,000 people). A CBSA contains one or more counties with an urban area of 10,000 or more people and the counties that have people who would commute to that area. There are over 900 CBSA codes used by the Medicare Program for the United States.

85. The territories to which Defendants assign their employed sales representatives and allied professionals are predicated on factors parallel to the CBSA territories. Defendants commonly assign their agents to work within a particular territory which corresponds to a CBSA territory.

86. Within each of the geographic clusters, there are facilities which have experienced generator replacement procedures at rates in excess of two standard deviations over the national average for one or more years during the time period of 2004-2008. Even after considering the national growth in the percent of generator replacement procedures and the major jump nationally in numbers of generator replacement procedures, there are eighteen clusters of facilities with generator replacement rates in excess of two standard deviations

beyond cohort averages. With respect to each of the standard deviations identified below, the results are statistically significant at a level of $p<.005$. There is less than ½ of 1 percent chance that the results were due to randomness.

87. Out of over 900 CBSAs in the United States, 18 CBSAs or regional clusters emerged with generator replacement rates repeatedly in excess of one or two standard deviations over the cohort averages. Excessive generator replacement rates in these 18 clusters represent damages to the Medicare Program in excess of 80 million dollars and represent thousands of unnecessary surgical procedures upon elderly patients with underlying cardiac conditions.

88. The initial dataset analyzed by Mr. Stokes included information on 3,291 United States hospitals with at least one new pacemaker implant between the years of 2004 and 2008. In total, these hospitals performed 887,453 new pacemaker implants between 2004 and 2008.

89. Using new implant volume in 2004 as a proxy for heart vascular program maturity, Mr. Stokes excluded 2,573 hospitals (78%) whose 2004 total case volume was less than 100 cases. This exclusion was designed to eliminate variability in the cohort due to clinical inexperience. The remaining 718 United States hospitals performed 616,321 new pacemaker implants between the years

2004 and 2008, representing 69.4% of the new pacemaker implant volume in the initial dataset.

90. Using total new implant volume as a proxy for heart and vascular program stability, Mr. Stokes then excluded an additional 146 US hospitals (4.4%) whose five-year total new implant volume was less than 500 cases. This exclusion was designed to eliminate variability in the cohort due to stagnant or declining volumes, which would presumably increase volumes at neighboring competitive facilities.

91. The final cohort is comprised of 572 United States hospitals, representing 17.38% of the initial dataset. These 572 hospitals collectively performed 555,308 new pacemaker implants between the years 2004 and 2008, representing 62.6% of the new pacemaker implant volume in the initial dataset.

92. In analyzing the growth rates for new implant procedures, a facility would not be expected to have low rates of growth with new devices, yet high rates of growth for replacement procedures as compared to national norms. Such a picture is inconsistent with expected market trending. Yet that has happened in the clustered locations discussed below. The clusters evidence a recurring pattern of total pacemaker cases declining or remaining stable while generator replacement procedures soared in numbers during the five-year period.

93. During this 5 year period, at these 572 hospitals, the national average rate of pacemaker replacement procedures per year doubled from a low of 14.2 percent of total pacemaker cases in 2004 to a high of 28.5 percent of total pacemaker cases in 2008.

94. On a facility level, the five-year rate of generator replacement procedures varied from a low of 1.16 percent to a high of 39.89 percent of total pacemaker cases.

95. The facilities where replacement procedure rates exceeded two standard deviations beyond cohort averages are commonly surrounded by other facilities also exhibiting replacement rates exceeding at least one or two standard deviations beyond cohort averages.

96. Mr. Stokes' extensive analyses are summarized and compiled within the Excel spreadsheets provided to the Department of Justice.

Introduction to Geographic Clusters with Replacement Rates in Excess of Two Standard Deviations Beyond the Cohort Average

Cluster One in the Miami-Fort Lauderdale-Miami Beach, Florida CBSA

97. Mr. Stokes' investigation and analyses reveal a cluster of statistically significant excessive replacement rates in the Miami-Fort Lauderdale-Miami

Beach, Florida CBSA. That cluster is composed of two hospitals with replacement rates repeatedly in excess of two standard deviations beyond cohort averages and five additional facilities which have repeatedly experienced replacement rates in excess of one standard deviation beyond cohort averages for the five year period of 2004-2008.

98. The two hospitals where replacement rates have repeatedly exceeded two standard deviations beyond the cohort averages for the final cohort of 572 facilities are Delray Medical Center and Holy Cross Hospital. The five facilities with replacement rates exceeding one standard deviation beyond cohort averages are Aventura Hospital and Medical Center, Palm Beach Gardens Medical Center, Baptist Hospital of Miami, Memorial Regional Hospital, and JFK Medical Center. All of these facilities are located within the same CBSA named Miami-Fort Lauderdale-Miami Beach.

99. All seven of these facilities within the Miami cluster had replacement rates which repeatedly exceeded one or two standard deviations beyond the cohort averages during the five year period of 2004-2008.

Delray Medical Center

100. At Delray Medical Center, generator replacement rates have been consistently excessive at compared to cohort and national averages. Between

2004 and 2008, generator replacement rates moved from 28 percent of total cases in 2004, 41.26 percent of total cases in 2005, 40.14 percent in 2006, 45.64 percent in 2007 to 45.37 percent in 2008. The five-year replacement rate at Delray Medical Center is double the national average at 39.5 percent of total pacemaker cases. While consistently excessive every year of the five year period, the generator replacement rates surged at Delray Medical Center between 2004 and 2008. In 2004, there were 494 total pacemaker cases, including 136 generator replacement procedures. By 2008, total pacemaker cases declined from 494 to 493 cases, yet generator replacement procedures surged from 136 procedures in 2004 to 201 procedures in 2008.

101. As mentioned in 2004, Delray Medical Center had 494 total pacemaker cases, including 136 generator replacement cases. This represents a 28 percent generator replacement rate as compared to the national average of 12.59 percent among all hospitals. Thus, in 2004, Delray Medical Center's rate of generator replacements as a percent of total pacemaker cases was more than double the national average among all hospitals.

102. In 2005, there were 412 total pacemaker cases with 170 procedures for generator replacements, representing 41.26 percent of the total cases. The national average among all hospitals of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent. In 2005, the rate of generator

replacements as a percent of total pacemaker cases was again more than double the national average.

103. In 2005, Delray Medical Center experienced generator replacement rates in excess of two standard deviations over the national average in 2005. The results are statistically significant at a level of $p<.001$. There is less than ½ of 1 percent chance that the results were due to randomness.

104. In 2006, there were 431 total pacemaker cases. Among these 431 total cases, there were 173 procedures for generator replacements, representing 40.14 percent of the total pacemaker cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent. In 2006, Delray Medical Center's rate of generator replacements as a percent of total pacemaker cases was again approximately double the national average.

105. In 2007, there were 390 total pacemaker cases. Among these 390 total cases, there were 178 procedures for generator replacements, representing 45.64 percent of the total pacemaker cases at Delray Medical Center as compared to the national average of 26 percent.

106. In 2008, among 443 total pacemaker cases, 201 procedures were for generator replacements, representing 45.37 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

107. The five-year total of generator replacements as a percent of total pacemaker cases at Delray Medical Center was 39.5 percent as compared to the national average of 20.2 percent.

108. The aberrant rates of replacement procedures at Delray Medical Center mark a specific territory where other hospitals have experienced excessive rates of generator replacement procedures.

Holy Cross Hospital---Miami, Florida

109. In the same CBSA as Delray Medical Center, Holy Cross Hospital experienced generator replacement rates in excess of two standard deviations over the national cohort average in 2004 and 2006. The results are statistically significant at a level of $p<.005$. There is less than 1 percent chance that the results were due to randomness

110. Holy Cross Hospital had 234 total pacemaker cases in 2004. Among these 234 cases, 77 procedures were for generator replacements, representing 33 percent of cases as compared to the national average of 12.59 percent.

111. In 2005, among 220 total pacemaker cases, 81 procedures were for generator replacements, representing 36.82 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

112. In 2006, among 201 total pacemaker cases, 82 procedures were for generator replacements, representing 40.80 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent. For three consecutive years, the rates of generator replacement procedures at Holy Cross were double the national average.

113. In 2007, among 181 total pacemaker cases, 67 procedures were for generator replacements, representing 37.02 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

114. In 2008, among 195 total pacemaker cases, 74 procedures were for generator replacements, representing 37.95 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

115. The five-year total of generator replacements as a percent of pacemaker cases at Holy Cross Hospital was 37.0 percent as compared to the national average of 20.2 percent.

116. Other hospitals within the Miami CBSA have experienced aberrant rates of generator replacement procedures, further evidencing the cluster.

Palm Beach Gardens Medical Center

117. In 2006, 2007, and 2008, generator replacement rates at Palm Beach Gardens Medical Center repeatedly exceeded one standard deviation beyond the national average among the final cohort of 572 hospitals.

118. Palm Beach Gardens Medical Center had 291 total pacemaker cases in 2004. Among these 291 cases, at least 42 procedures were for generator replacements in pacemakers, representing 14.43 percent of total cases which was close to the national average of 12.59 percent for all hospitals.

119. In 2005, among 304 total pacemaker cases, 61 procedures were for generator replacements, representing 20.07 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

120. In 2006, among 244 total pacemaker cases, 91 procedures were for generator replacements, representing 37.30 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent. Between 2004 and 2006, total pacemaker cases declined from 291 cases in 2004 to 244 cases in 2006. Yet generator replacement procedures more than doubled from 42 procedures in 2004 to 91 procedures in 2006.

121. In 2007, among 259 total pacemaker cases, 100 procedures were for generator replacements, representing 38.61 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

122. In 2008, among 270 total pacemaker cases, 108 procedures were for generator replacements, representing 40.00 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

123. Between 2004 and 2008, total pacemaker cases at Palm Beach Gardens Medical Center declined from 291 to 270 cases, yet generator replacement procedures surged from 42 procedures in 2004 to 108 procedures in 2008.

124. Between 2004 and 2008, the replacement rate percent at Palm Beach Gardens Medical Center moved from 14.43 percent to 40 percent of total cases.

125. The five-year average growth per year in generator replacements at Palm Beach Gardens Medical Center was 21 percent or nearly the double the national average of 10.08 percent.

JFK Medical Center

126. In the same Miami CBSA, although JFK Medical Center exceeded one standard deviation in only one of the five years, the jump in replacement rates remains significant.

127. At JFK Medical Center, the replacement rate percent moved from 10.5 percent of total pacemaker cases in 2004 to 21.53 percent in 2005, 31.78 percent in 2006, 33.23 percent in 2007, and 35.61 percent in 2008.

128. In 2004 there were 381 total pacemaker cases and only 40 replacement procedures at JFK Medical Center. In 2008 there were 337 total pacemaker cases and 120 generator replacement procedures at JFK. Comparing 2004 and 2008, while total pacemaker cases declined from 381 to 337 cases, generator replacement procedures tripled in number.

Baptist Hospital of Miami

129. At Baptist Hospital of Miami, the replacement rate percent moved from 12.68 percent of total pacemaker cases in 2004 to 28.48 percent in 2005, 26.56 percent in 2006, 42.76 percent in 2007, and 39.05 percent in 2008.

130. In 2004 there were 205 total pacemaker cases with only 26 replacement procedures at Baptist Hospital of Miami. In 2008 there were 169 total pacemaker cases and 66 generator replacement procedures at Baptist Hospital

of Miami. Comparing 2004 and 2008, while total pacemaker cases declined, generator replacement procedures increased by 250 percent.

Boca Raton Community Hospital

131. In the same Miami CBSA, at Boca Raton Community Hospital, the replacement rate percent moved from 15.50 percent of total pacemaker cases in 2004 to 34.86 percent of total cases in 2007.

132. In 2004, there were 413 total pacemaker cases at Boca Raton Community Hospital with only 64 replacement procedures. In 2007 there were fewer total pacemaker cases (350) but nearly double the number of replacement procedures (122) as compared to 2004. [3]

Aventura Hospital and Medical Center

133. In the same Miami CBSA, replacement rates at Aventura Hospital and Medical Center moved from 19.29 percent of total cases in 2004 to 42.95 percent of total cases in 2007. In 2004, there were 140 total pacemaker cases

[3] In close proximity to the Miami cluster is another location approximately 100 miles away in Stuart, Florida which experienced replacement rates in excess of one standard deviation for four consecutive years between 2005 and 2008.

At Martin Memorial Medical Center, the replacement rates moved from 11.84 percent of total cases in 2004 to 32.50 percent in 2005, 35.45 percent in 2006, 37.91 percent in 2007, and 46.63 percent in 2008.

at Aventura Hospital with only 27 replacement procedures. In 2005, there were 131 total pacemaker cases with 35 replacement procedures. In 2007 total pacemaker cases remained close to the level of 2004 at 149 cases. Yet replacement procedures increased from 27 procedures in 2004 to 64 procedures in 2007.

Mercy Hospital

134. In the same Miami CBSA, replacement rates at Mercy Hospital moved from 17.03 percent of total cases in 2004 to 47.01 percent of total cases in 2008. In 2004, there were 229 total pacemaker cases at Mercy Hospital with only 39 replacement procedures. In 2006, there were 181 total pacemaker cases with 39 replacement procedures again. Yet in 2008, total pacemaker cases declined significantly to 135 cases while replacement procedures surged to 64 procedures.

Cluster Two in the New York-Northern New Jersey-Long Island CBSA

135. Within the New York-Northern New Jersey-Long Island CBSA, multiple hospitals have experienced replacement rates in excess of one and two standard deviations over cohort averages. Within the same CBSA, three hospitals have experienced annual replacement rates in excess of two standard

deviations and six other hospitals have repeatedly experienced replacement rates in excess of one standard deviation over the time period of 2004-2008.

136. The three hospitals within this CBSA which have experienced annual replacement rates in excess of two standard deviations above the cohort average are Newark Beth Israel Medical Center, New York Hospital Queens, and Huntington Hospital.

137. In 2004 and 2006, New York Hospital Queens experienced generator replacement rates in excess of two standard deviations over the cohort average and also experienced generator replacement rates in excess of one standard deviation over the cohort average in 2007.

138. In 2005, Newark Beth Israel Medical Center experienced generator replacement rates in excess of two standard deviations over the cohort average and also experienced generator replacement rates in excess of one standard deviation over the cohort average in 2004 and 2006.

139. Within the same CBSA, Saint Barnabas Medical Center and New York Presbyterian Hospital experienced generator replacement rates in excess of one standard deviation over the cohort average for three of the five years.

140. Within the same CBSA, Saint Francis Hospital experienced replacement rates in excess of one standard deviation every year for five consecutive years, 2004-2008.

Saint Francis Hospital

141. In 2004 Saint Francis Hospital had 895 total pacemaker cases. Among these 895 cases, 233 procedures were for generator replacements in pacemakers, representing 26 percent of cases as compared to the national average of 12.59 percent among all hospitals.

142. In 2005, among 622 total pacemaker cases, 208 procedures were for generator replacements, representing 33.44 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

143. In 2006, among 625 total pacemaker cases, 214 procedures were for generator replacements, representing 34.24 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

144. In 2007, among 539 total pacemaker cases, 240 procedures were for generator replacements, representing 44.53 percent of the cases as compared to the national average of 26 percent.

145. In 2008, among 522 total pacemaker cases, 243 procedures were for generator replacements, representing 46.55 percent of the cases as compared to the national average of 28 percent.

146. Between 2004 and 2008, total pacemaker cases at Saint Francis declined significantly from 895 cases in 2004 to 522 cases in 2008. Yet generator replacement procedures increased from 233 to 243 procedures. Between 2004 and 2008, generator replacement procedures moved from 26 percent of total cases to 46 percent of total cases at Saint Francis Hospital.

147. The five-year rate of generator replacements as a percent of pacemaker cases at Saint Francis Hospital was 35.5 percent as compared to the national average of 20.2 percent.

New York Presbyterian Hospital

148. In the same New York CBSA, New York Presbyterian Hospital had 613 total pacemaker cases in 2004. Among these 613 cases, 125 procedures were for generator replacements in pacemakers, representing 20.39 percent of the total cases as compared to the national average of 12.59 percent among all hospitals.

149. In 2005, among 533 total pacemaker cases, 166 procedures were for generator replacements, representing 31.14 percent of the total cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent. Between 2004 and 2005, total pacemaker cases

declined from 613 to 533, yet replacement procedures climbed from 125 procedures in 2004 to 166 procedures in 2005.

150. In 2006, among 442 total pacemaker cases, 144 procedures were for generator replacements, representing 32.58 percent of the cases as compared to the national average of 20 percent.

151. In 2007, among 525 total pacemaker cases, 191 procedures were for generator replacements, representing 36.38 percent of the cases as compared to the national average of 26 percent.

152. In 2008, there were 484 total pacemaker cases at New York Presbyterian Hospital with 200 replacement procedures, representing 41.32 percent of the cases.

153. Between 2004 and 2008, total pacemaker cases declined from 613 cases in 2004 to 484 cases in 2008. Yet replacement procedures escalated from 125 procedures in 2004 to 200 procedures in 2008. Between 2004 and 2008, the replacement rate at New York Presbyterian Hospital moved from 20.39 percent of total cases in 2004 to 41.32 percent of total cases in 2008.

154. The five-year rate of generator replacements as a percent of pacemaker cases at New York Presbyterian Hospital was 31.81 percent as compared to the national average of 20.2 percent.

New York Hospital Queens

155. In the same New York CBSA, New York Hospital Queens had 202 total pacemaker cases in 2004. Among these 202 cases, 60 procedures were for generator replacements in pacemakers, representing 29.70 percent of cases or over double the national average of 12.59 percent among all hospitals.

156. In 2005, among 163 total pacemaker cases, 46 procedures were for generator replacements, representing 28.22 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

157. In 2006, among 136 total pacemaker cases, 54 procedures were for generator replacements, representing 39.71 percent of the cases or nearly double the national average of generator replacements as a percent of total pacemaker cases.

158. In 2007, among 180 total pacemaker cases, 72 procedures were for generator replacements, representing 40 percent of the cases as compared to the national average of 26 percent.

159. The five-year rate of generator replacements as a percent of pacemaker cases at New York Hospital Queens was 33.21 percent as compared to the national average of 20.2 percent.

Newark Beth Israel Medical Center

160. In the same New York CBSA, Newark Beth Israel Medical Center had 170 total pacemaker cases in 2004. Among these 170 cases, 48 procedures were for generator replacements in pacemakers, representing 28.24 percent of the total cases or over double the national average of 12.59 percent among all hospitals.

161. In 2005, among 165 total pacemaker cases, 72 procedures were for generator replacements, representing 43.64 percent of the total cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

162. In 2006, among 123 total pacemaker cases, 40 procedures were for generator replacements, representing 32.52 percent of the total cases as compared to the 20 percent national average.

163. In 2007, among 113 total pacemaker cases, 41 procedures were for generator replacements, representing 36.28 percent of the total cases as compared to the national average of 26 percent.

164. The five-year rate of generator replacements as a percent of pacemaker cases at Newark Beth Israel Medical Center was 34.91 percent as compared to the national average of 20.2 percent.

Somerset Medical Center

165. In the same New York CBSA, replacement rates at Somerset Medical Center exceeded one standard deviation in only one of the five years (2008); however, the jump in replacement procedures over the five-year period is significant.

166. In 2004, there were 127 total pacemaker cases at Somerset with only 10 replacement procedures, representing 7.87 percent of the cases. By 2008, total pacemaker cases declined slightly to 119 cases; however, replacement procedures surged to 56 procedures as compared to 10 procedures in 2004.

167. Between 2004 and 2008, replacement rates at Somerset moved from 7.87 percent of total pacemaker cases in 2004 to 47.06 percent of total pacemaker cases in 2008.

Saint Barnabas Medical Center

168. In the same New York CBSA, at Saint Barnabas Medical Center there were 255 total pacemaker cases with 55 generator replacement procedures in 2004, representing 21.57 percent of the cases.

169. In the next year, total pacemaker cases declined from 255 to 233 cases, yet generator replacement procedures increased from 55 to 68 procedures, representing 29.18 percent of cases.

170. By 2007, total pacemaker cases declined further to 182 cases, yet generator replacement procedures remained at 68 procedures, representing 37.36 percent of cases. Between 2004 and 2007, generator replacement procedures jumped from 21.57 percent of total cases to 37.36 percent of total cases.

171. In 2008, total pacemaker cases returned close to the level in 2004 at 255 cases. Yet generator replacement procedures had moved from 55 procedures in 2004 to 80 procedures in 2008.

New York University Elaine and Kenneth G. Langone Medical Center

172. In the same New York CBSA, at Langone Medical Center, there were 231 total pacemaker cases with 46 generator replacement procedures, representing 19.91 percent of the total cases in 2004.

173. In 2005 at Langone Medical Center, there were 206 total pacemaker cases with 35 generator replacement procedures, representing 16.99 percent of the cases.

174. In 2006 at Langone Medical Center, there were 181 total pacemaker cases with 39 generator replacement procedures, representing 21.55 percent of the cases.

175. Yet in 2007, total pacemaker cases declined to a four-year low at 173, while generator replacement procedures climbed to a four-year high at 61 procedures or 35.26 percent of the cases.

176. That escalation in generator replacement procedures continued into 2008 with 269 total pacemaker cases and 107 generator replacement procedures or 39.78 percent.

Cluster Three in the Los Angeles-Long Beach-Santa Ana, California CBSA

177. Two hospitals in the Los Angeles-Long Beach-Santa Ana CBSA led the cluster with replacement rates repeatedly in excess of two standard deviations over cohort averages. Seven other hospitals within this CBSA experienced replacement rates repeatedly in excess of one standard deviation beyond cohort averages.

Providence Tarzana Medical Center

178. The replacement rates at Providence Tarzana Medical Center exceeded two standard deviations in 2005 and exceeded one standard deviation over the cohort averages in 2004, 2006, and 2007.

179. Providence Tarzana Medical Center had 173 total pacemaker cases in 2004. Among these 173 cases, 45 procedures were for generator replacements

in pacemakers, representing 26 percent of total cases. The national average was 12.59 percent among all hospitals.

180. In 2005, among 187 total pacemaker cases, 76 procedures were for generator replacements, representing 40.64 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

181. In 2006, among 190 total pacemaker cases, 62 procedures were for generator replacements, representing 32.63 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

182. In 2007, among 200 total pacemaker cases, 73 procedures were for generator replacements, representing 36.50 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

183. The five-year total of generator replacements as a percent of pacemaker cases at Providence Tarzana was 32.4 percent as compared to the national average of 20.2 percent.

Providence Saint Joseph Medical Center

184. Within the same Los Angeles CBSA, the replacement rates at Saint Joseph Medical Center exceeded one standard deviation over cohort averages in 2004, 2005, and 2006.

185. In 2004, Providence Saint Joseph Medical Center had 159 total pacemaker cases. Among these 159 cases, 39 procedures were for generator replacements in pacemakers, representing 25 percent of cases as compared to the national average of 12.59 percent among all hospitals.

186. In 2005, among 121 total pacemaker cases, 40 procedures were for generator replacements, representing 33.06 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

187. In 2006, among 127 total pacemaker cases, 42 procedures were for generator replacements, representing 33.07 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

188. In 2007, among 95 total pacemaker cases, 34 procedures were for generator replacements, representing 35.79 percent of the cases.

189. In 2008, among 115 total pacemaker cases, 41 procedures were for generator replacements, representing 35.65 percent of the cases.

190. The five-year rate of generator replacements as a percent of pacemaker cases at Providence Saint Joseph Medical Center was 31.8 percent as compared to the national average of 20.2 percent.

Cedars-Sinai Medical Center

191. Within the Los Angeles CBSA, the replacement rates at Cedars-Sinai Medical Center exceeded one standard deviation over cohort averages in 2005, 2006, and 2007.

192. In 2004, Cedar-Sinai Medical Center had 480 total pacemaker cases. Among these 480 cases, 93 procedures were for generator replacements in pacemakers, representing 19 percent of cases as compared to the national average of 12.59 percent.

193. In 2005, among 430 total pacemaker cases, 145 procedures were for generator replacements, representing 33.72 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent. Between 2004 and 2005, total pacemaker cases declined from 480 to 430 cases, yet generator replacement procedures surged from 93 procedures in 2004 to 145 procedures in 2005.

194. In 2006, among 417 total pacemaker cases, 145 procedures were for generator replacements, representing 34.77 percent of the cases. The national

average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

195. In 2007, among 367 total pacemaker cases, 149 procedures were for generator replacements, representing 34.65 percent of the cases as compared to the national average of 26 percent.

196. In 2008, among 404 total pacemaker cases, 140 procedures were for generator replacements, representing 35.65 percent of the cases.

197. In 2004, there were 480 total pacemaker cases and 93 replacement procedures. By 2007, total pacemaker cases declined by 113 while generator replacement procedures increased by 56.

198. Over the five year period from 2004-2008, the percentage of replacement procedures as compared to pacemaker cases at Cedars-Sinai Medical Center jumped from 19.38 percent in 2004 to 33.72 percent in 2005, 34.77 percent in 2006, 40.60 percent in 2007, and 34.65 percent in 2008

Torrance Memorial Medical Center

199. Within the same Los Angeles CBSA, the replacement rates at Torrance Memorial Medical Center repeatedly exceeded two standard deviations beyond the cohort average in 2004, 2006, and 2007. In 2005, the replacement rates at

Torrance Memorial exceeded one standard deviation beyond the cohort average.

200. Torrance Memorial Medical Center had 110 total pacemaker cases in 2004. Among these 110 cases, 38 procedures were for generator replacements in pacemakers, representing 35 percent of cases as compared to the national average of 12.59 percent among all hospitals.

201. In 2005, among 79 total pacemaker cases, 28 procedures were for generator replacements, representing 35.44 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

202. In 2006, among 112 total pacemaker cases, 53 procedures were for generator replacements, representing 47.32 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

203. In 2007, among 124 total pacemaker cases, 59 procedures were for generator replacements, representing 47.58 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

204. In 2008, among 114 total pacemaker cases, 37 procedures were for generator replacements, representing 32.46 percent of the cases.

205. The five-year rate of generator replacements as a percent of pacemaker cases at Torrance Memorial Medical Center was 39.9 percent as compared to the national average of 20.2 percent.

Hoag Memorial Hospital

206. In the same Los Angeles CBSA, Hoag Memorial Hospital experienced generator replacement rates in excess of one standard deviation in 2005, 2006, and 2008.

207. In 2004, there were 208 total pacemaker cases at Hoag Memorial Hospital. Among these 208 total cases, 28 procedures were for pacemaker generator replacements, representing 13.46 percent of the total cases which was close to the national average of 12.59 percent.

208. In 2005, there were 197 total pacemaker cases at Hoag Memorial Hospital. Among these 197 total cases, 61 procedures were for pacemaker generator replacements, representing 30.96 percent of the cases as compared to the national average of 18 percent.

209. Between 2004 and 2005, total pacemaker cases remained stable, yet replacement procedures more than doubled, moving from 13.46 percent of total cases in 2004 to 30.96 percent of total cases in 2005.

210. In 2006, there were 212 total pacemaker cases at Hoag Memorial Hospital. Among these 212 total cases, 74 procedures were for pacemaker generator replacements, representing 34.91 percent of the total cases as compared to the national average of 20 percent.

211. In 2007, there were 204 total pacemaker cases at Hoag Memorial Hospital. Among these 204 total cases, 69 procedures were for pacemaker generator replacements, representing 33.82 percent of the cases.

212. In 2008, there were 175 total pacemaker cases at Hoag Memorial Hospital. Among these 175 total cases, 67 procedures were for pacemaker generator replacements, representing 38.29 percent of the cases.

213. Between 2004 and 2008, generator replacement procedures jumped from 13.46 percent of total cases to 38.29 percent of total cases at Hoag Memorial Hospital.

Methodist Hospital

214. In the same Los Angeles CBSA, the replacement rates at Methodist Hospital exceeded one standard deviation in only one year (2008); however, the jumps in replacement procedures provide further evidence of the cluster.

215. In 2004, there were 121 total pacemaker cases at Methodist Hospital. Among these 121 total cases, 24 procedures were for pacemaker generator

replacements, representing 19.83 percent of the cases as compared to the national average of 12.59 percent.

216. In 2005, there were 122 total pacemaker cases at Methodist Hospital. Among these 122 total cases, 26 procedures were for pacemaker generator replacements, representing 21.31 percent of the total cases.

217. In 2006, there were 113 total pacemaker cases at Methodist Hospital. Among these 113 total cases, only 15 procedures were for pacemaker generator replacements, representing 13.27 percent of the total cases.

218. Yet in 2007, among 143 total pacemaker cases, 46 procedures were for pacemaker generator replacements, representing 32.17 percent of the cases. In a single year, generator replacement procedures moved from 13.27 percent to 32.17 percent of total pacemaker cases at Methodist Hospital.

219. The escalation in replacement procedures continued in 2008. In 2008, there were 161 total pacemaker cases at Methodist Hospital. Among these 161 total cases, 64 procedures were for pacemaker generator replacements, representing 39.75 percent of the cases. Between 2006 and 2008, generator replacement procedures moved from 13.27 percent of total cases to 39.75 percent of total cases at Methodist Hospital.

Cluster Four in Louisville-Jefferson County, Ky-In CBSA

220. Mr. Stokes' analyses reveal a three-hospital cluster from the Louisville CBSA led by Baptist Hospital East which repeatedly experienced replacement rates in excess of one or two standard deviations over the cohort averages. In 2004, 2005, 2006, and 2008, Baptist Hospital East experienced replacement rates in excess of one standard deviation beyond the cohort average. In 2007, Baptist Hospital East's replacement rates exceeded two standard deviations.

Baptist Hospital East

221. In 2004, Baptist Hospital East had 283 total pacemaker cases. Among these 283 cases, 63 procedures were for generator replacements in pacemakers, representing 22 percent of cases as compared to the national average of 12.59.

222. In 2005, among 286 total pacemaker cases, 96 procedures were for generator replacements, representing 33.57 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

223. In 2006, among 294 total pacemaker cases, 109 procedures were for generator replacements, representing 37.07 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

224. In 2007, among 277 total pacemaker cases, 148 procedures were for generator replacements, representing 53.43 percent of the cases as compared to the national average of 26 percent.

225. Between 2004 and 2007, total pacemaker cases slightly declined from 283 to 277, yet replacement procedures escalated from 63 to 148 procedures.

226. Between 2004 and 2007, replacement procedures moved from 22 percent of total cases in 2004 to 53.43 percent of cases in 2007.

227. In 2008, among 259 total pacemaker cases, 105 procedures were for generator replacements, representing 40.54 percent of the cases as compared to the national average of 28 percent.

228. The five-year rate of generator replacements as a percent of pacemaker cases at Baptist Hospital East was 37.2 percent as compared to the national average of 22.28 percent.

Jewish Hospital and Norton Hospital

229. In the same Louisville CBSA is Jewish Hospital and Norton Hospital which both repeatedly experienced replacement rates in excess of one standard deviation beyond cohort averages.

230. At Jewish Hospital, replacement rates moved from 15.62 percent of total cases in 2004 to 31.52 percent of total cases in 2005, 30.71 percent in 2006, 30.95 percent in 2007, and 33.65 percent in 2008.

231. The replacement rates at Norton Hospital exceeded one standard deviation every year except 2005. The replacement rate percents at Norton Hospital were 26.56 of total cases in 2004, 28.49 percent in 2005, 30.47 percent in 2006, 40.34 percent in 2007, and 38.30 percent in 2008.

Adjacent Facilities with Excessive Replacement Rates

232. Close to the cluster in the Louisville CBSA is Owensboro Medical Center which experienced generator replacement rates in excess of one standard deviation over cohort averages in 2004, 2005, and 2006.

233. Also close to the Louisville cluster is Kettering Medical Center where generator replacement rates moved from 17.56 percent of total cases in 2004 to 40.40 percent of total cases in 2008. Comparing 2004 and 2008 at Kettering Medical Center, total cases remained stable with 205 cases in 2004 and 198 cases in 2008. Yet generator replacement procedures surged from 35 procedures in 2004 to 80 procedures in 2008.

Cluster Five in the Birmingham-Hoover, Alabama CBSA

234. In 2004 and 2007, the replacement rates at Trinity Medical Center exceeded two standard deviations over the cohort average. In 2005 and 2006, the replacement rates at Trinity Medical exceeded one standard deviation over the cohort average. Within the same Birmingham-Hoover CBSA, Trinity Medical Center is joined by two other facilities which repeatedly experienced replacement rates in excess of one or two standard deviations over cohort averages.

Trinity Medical Center

235. In 2004, Trinity Medical Center had 225 total pacemaker cases. Among these 225 cases, 65 procedures were for generator replacements in pacemakers, representing 29 percent of cases as compared to the national average of 12.59 percent among all hospitals.

236. In 2005, among 186 total pacemaker cases, 54 procedures were for generator replacements, representing 29.03 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

237. In 2006, among 155 total pacemaker cases, 58 procedures were for generator replacements, representing 37.42 percent of the cases. The national

average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

238. In 2007, among 146 total pacemaker cases, 78 procedures were for generator replacements, representing 53.42 percent of the cases as compared to the national average of 26 percent.

239. Between 2005 and 2007, generator replacement rates at Trinity Medical Center moved from 29.03 percent to 53.42 percent of total pacemaker cases.

240. In 2008, among 142 total pacemaker cases, 52 procedures were for generator replacements, representing 36.62 percent of the cases as compared to the national average of 28 percent.

241. The five-year rate of generator replacements as a percent of pacemaker cases at Trinity Medical Center was 35.9 percent as compared to the national average of 20.2 percent.

Princeton Baptist Hospital

242. Within the same Birmingham CBSA, Princeton Baptist Hospital's replacement rates exceeded one standard deviation in both 2004 and 2005 and exceeded two standard deviations in 2006.

243. Princeton Baptist Hospital had 157 total pacemaker cases in 2004. Among these 157 cases, at least 42 procedures were for generator replacements

in pacemakers, representing 27 percent of cases as compared to the national average of 12.59.

244. In 2005, among 135 total pacemaker cases, 50 procedures were for generator replacements, representing 37.04 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

245. In 2006, among 119 total pacemaker cases, 47 procedures were for generator replacements, representing 39.50 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

UAB Hospital---Birmingham, Alabama

246. Within the same Birmingham CBSA, UAB Hospital had 103 total pacemaker cases in 2004. Among these 103 cases, 25 procedures were for generator replacements in pacemakers, representing 24 percent of cases as compared to the national average of 12.59 percent among all hospitals.

247. In 2005, among 118 total pacemaker cases, 45 procedures were for generator replacements, representing 38.14 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

248. In 2006, among 151 total pacemaker cases, 54 procedures were for generator replacements, representing 35.76 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

249. In 2007, among 162 total pacemaker cases, 47 procedures were for generator replacements, representing 29.01 percent of the cases.

250. In 2008, among 109 total pacemaker cases, 40 procedures were for generator replacements, representing 36.70 percent of the cases.

251. The five-year rate of generator replacements as a percent of pacemaker cases at UAB Hospital was 32.8 percent as compared to the national average of 20.2 percent.

Cluster Six in the Sarasota-Bradenton-Venice, Florida CBSA

Venice Regional Medical Center

252. The Sarasota-Bradenton-Venice CBSA includes one hospital with generator replacement rates in excess of two standard deviations beyond cohort averages and two other facilities with replacement rates which have repeatedly exceeded one standard deviation beyond cohort averages.

253. Venice Regional Medical Center experienced generator replacement rates in excess of two standard deviations over the cohort average in 2005.

254. Venice Regional Medical Center had 180 total pacemaker cases in 2004. Among these 180 cases, at least 45 procedures were for generator replacements in pacemakers, representing 25 percent of cases as compared to the national average of 12.59 percent among all hospitals.

255. In 2005, among 154 total pacemaker cases, 63 procedures were for generator replacements, representing 40.91 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent. In 2005, Venice Regional's rate of generator replacements as a percent of total pacemaker cases was over double the national average.

256. In 2006, among 166 total pacemaker cases, 60 procedures were for generator replacements, representing 36.14 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

257. In 2007, among 193 total pacemaker cases, 64 procedures were for generator replacements, representing 33.16 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

258. In 2008, among 192 total pacemaker cases, 67 procedures were for generator replacements, representing 34.90 percent of the cases. The national

average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

259. The five-year total of generator replacements as a percent of pacemaker cases at Venice Regional Medical Center was 33.8 percent as compared to the national average of 20.2 percent.

Sarasota Memorial Hospital

260. Within the same CBSA in close proximity to Venice Regional Medical Center is Sarasota Memorial Hospital which experienced generator replacement rate in excess of one standard deviation over cohort averages for five consecutive years: 2004, 2005, 2006, 2007, and 2008.

261. Sarasota Memorial Hospital had 586 total pacemaker cases in 2004. Among these 586 cases, at least 129 procedures were for generator replacements in pacemakers, representing 22 percent of cases as compared to the national average of 12.59 percent among all hospitals.

262. In 2005, among 509 total pacemaker cases, 166 procedures were for generator replacements, representing 32.61 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

263. In 2006, among 438 total pacemaker cases, 157 procedures were for generator replacements, representing 35.84 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

264. In 2007, among 483 total pacemaker cases, 197 procedures were for generator replacements, representing 40.79 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

265. Between 2004 and 2007, replacement rates at Sarasota Memorial Hospital surged from 22 percent of total cases in 2004 to 40.79 percent of total cases in 2007.

266. Between 2004 and 2007, total pacemaker cases declined from 586 to 493 cases, yet generator replacement procedures escalated from 129 to 197 procedures at Sarasota Memorial Hospital.

267. In 2008, among 427 total pacemaker cases, 167 procedures were for generator replacements, representing 39.11 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

268. The five-year total of generator replacements as a percent of pacemaker cases at Sarasota Memorial Hospital was 33.4 percent as compared to the national average of 20.2 percent.

Manatee Memorial Hospital

269. Within the same CBSA and in close proximity, Manatee Memorial Hospital also experienced a significant surge in replacement procedures, moving from 12.22 percent of total pacemaker cases in 2004 to 20.2 percent in 2005, 30.83 percent in 2006, 39.26 percent in 2007, and 38.94 percent in 2008.

Cluster Seven in Cape Coral-Fort Myers CBSA

Lee Memorial Hospital and Gulf Coast Medical Center

270. In close proximity to the cluster in the Sarasota-Bradenton-Venice CBSA is another cluster in the Cape Coral-Fort Myers CBSA. Lee Memorial Hospital and Gulf Coast Medical Center are both part of the Lee Memorial Health System. For four of the five years, Lee Memorial Hospital experienced replacement rates in excess of one standard deviation over cohort averages. Gulf Coast Medical Center's replacement rates exceeded one standard deviation in 2007 and two standard deviations in 2008.

271. For example, Lee Memorial Hospital had 283 total pacemaker cases in 2004. Among these 283 cases, at least 80 procedures were for generator replacements in pacemakers, representing 28 percent of cases as compared to the national average of 12.59 percent among all hospitals.

272. In 2005, among 291 total pacemaker cases, 88 procedures were for generator replacements, representing 30.24 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

273. In 2006, among 265 total pacemaker cases, 88 procedures were for generator replacements, representing 33.21 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

274. In 2007, among 288 total pacemaker cases, 111 procedures were for generator replacements, representing 38.54 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

275. In close proximity to Lee Memorial Hospital, Gulf Coast Medical Center's replacement rates moved from 11.76 percent of total cases in 2004, to 19.78 percent in 2005, 22.81 percent in 2006, 37.98 percent in 2007, and 65 percent in 2008.

Cluster Eight in Santa Barbara –Santa Maria, California CBSA

276. Mr. Stokes' investigation and analyses reveal another cluster in the Santa Barbara-Santa Maria, California CBSA.

Santa Barbara Cottage Hospital

277. The replacement rates at Santa Barbara Cottage Hospital have repeatedly exceeded one or two standard deviations over cohort averages for five consecutive years: 2004, 2005, 2006, 2007, and 2008. In 2005 and 2008, the replacement rates at Santa Barbara Cottage Hospital exceeded two standard deviations. In 2004, 2006, and 2007, the replacement rates at Santa Barbara Cottage Hospital exceeded one standard deviation.

278. Santa Barbara Cottage Hospital had 284 total pacemaker cases in 2004. Among these 284 cases, at least 67 procedures were for generator replacements in pacemakers, representing 23.59 percent of cases as compared to the national average of 12.59 percent among all hospitals. In 2004, Santa Barbara Cottage Hospital's rate of generator replacements as a percent of total pacemaker cases was nearly double the national average among all hospitals.

279. In 2005, among 207 total pacemaker cases, 79 procedures at Santa Barbara Cottage Hospital were for generator replacements, representing 38.16 percent of the cases. The national average among all hospitals of generator

replacements as a percent of total pacemaker cases in 2005 was 18 percent. In 2005, Santa Barbara Cottage Hospital's rate of generator replacements as a percent of total pacemaker cases was again double the national average.

280. In 2006, among 238 total pacemaker cases, 77 procedures were for generator replacements, representing 32.35 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

281. In 2007, among 271 total pacemaker cases, 121 procedures were for generator replacements, representing 44.65 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

282. Between 2004 and 2007, total pacemaker cases at Santa Barbara Cottage Hospital declined slightly from 284 to 271 cases, yet generator replacement procedures nearly doubled from 67 to 121 procedures.

283. In 2008, among 198 total pacemaker cases, 98 procedures were for generator replacements, representing 49.49 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

284. The five-year total of generator replacements as a percent of pacemaker cases at Santa Barbara Cottage Hospital was 36.89 percent as compared to the national average of 20.2 percent.

Marian Medical Center

285. In the same CBSA is Marian Medical Center which experienced replacement rates in excess of one standard deviation in 2006 and in excess of two standard deviations in 2007. Between 2004 and 2008, replacement rates at Marian Medical Center moved from 16.10 percent of total cases in 2004 to 22.22 percent in 2005, 35.19 percent in 2006, 50.36 percent in 2007 and 35.48 percent in 2008.

286. In 2004, there were 135 total pacemaker cases with 22 generator replacement procedures at Marian Medical Center. By 2007, total pacemaker cases remained stable at 137 as compared to 135 in 2004. Yet in 2007, generator replacement procedures surged to 69 procedures as compared to 22 procedures in 2004.

Bakersfield Heart Hospital

287. In close proximity to Marian Medical Center and Santa Barbara Cottage Hospital but in a different CBSA, Bakersfield Heart Hospital experienced replacement rates replacement rates in excess of one standard deviation in

2004 and 2005 and in excess of two standard deviations in both 2006 and 2007.

288. In 2004 Bakersfield Heart Hospital had 151 total pacemaker cases. Among these 151 cases, 37 procedures were for generator replacements in pacemakers, representing 25 percent of cases as compared to the national average of 12.59 percent.

289. In 2005, among 110 total pacemaker cases, 37 procedures were for generator replacements, representing 33.64 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

290. In 2006, among 114 total pacemaker cases, 56 procedures were for generator replacements, representing 49.12 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

291. In 2007, among 122 total pacemaker cases, 63 procedures were for generator replacements, representing 51.64 percent of the cases as compared to the national average of 26 percent.

292. Between 2004 and 2007, total pacemaker cases declined from 151 cases in 2004 to 122 cases in 2007. Yet generator replacement procedures surged from 37 procedures in 2004 to 63 procedures in 2007.

293. In 2008, among 110 total pacemaker cases, 40 procedures were for generator replacements, representing 36.36 percent of the cases as compared to the national average of 28 percent.

294. The five-year rate of generator replacements as a percent of pacemaker cases at Bakersfield Heart Hospital was 38.4 percent as compared to the national average of 22.28 percent.

295. The five-year total generator replacement percent at Bakersfield Heart Hospital was 38.4 percent as compared to the national average of 20.2 percent.

Bakersfield Memorial Hospital

296. Within the same town and CBSA as Bakersfield Heart Hospital, the five-year total generator replacement percent at Bakersfield Memorial Hospital was also 38.4 percent as compared to the national average of 20.2 percent. Bakersfield Memorial Hospital did not reach the 500 threshold for total pacemaker cases over the 5 year period so it was not included in the cohort. Yet the surge in replacement procedures is significant.

297. In 2004, Bakersfield Memorial Hospital had 102 total pacemaker cases. Among these 102 cases, 23 procedures were for generator replacements in pacemakers, representing 23 percent of cases as compared to the national average of 12.59 percent.

298. In 2005, among 96 total pacemaker cases, 42 procedures were for generator replacements, representing 43.75 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

299. In 2006, among 110 total pacemaker cases, 47 procedures were for generator replacements, representing 42.73 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

300. Between 2004 and 2006, total pacemaker cases remained stable at 102 cases in 2004 and 110 cases in 2006. Yet generator replacement procedures doubled from 23 procedures in 2004 to 47 procedures in 2006.

301. In 2007, among 85 total pacemaker cases, 29 procedures were for generator replacements, representing 34.12 percent of the cases as compared to the national average of 26 percent.

302. In 2008, among 60 total pacemaker cases, 33 procedures were for generator replacements, representing 55 percent of the cases as compared to the national average of 28 percent.

303. The five-year rate of generator replacements as a percent of pacemaker cases at Bakersfield Memorial was 38.4 percent as compared to the national average of 20.2 percent.

Cluster Nine in Tucson Arizona CBSA

Tucson Heart Hospital

304. Tucson Heart Hospital experienced replacement rates in excess of two standard deviations beyond the cohort average in 2006 and 2007 and exceeded one standard deviation beyond the cohort average in 2008.

305. In 2004, Tucson Heart Hospital had 283 total pacemaker cases. Among these 283 cases, 55 procedures were for generator replacements, representing 19 percent of cases as compared to the national average of 12.59 percent.

306. In 2005, among 167 total pacemaker cases, 46 procedures were for generator replacements, representing 27.54 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

307. In 2006, among 214 total pacemaker cases, 94 procedures were for generator replacements, representing 43.93 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

308. Between 2004 and 2006, total pacemaker cases declined from 283 cases in 2004 to 214 cases in 2006. Yet generator replacement procedures surged from 55 procedures in 2004 to 94 procedures in 2006.

309. In 2007, among 226 total pacemaker cases, 104 procedures were for generator replacements, representing 46.02 percent of the cases as compared to the national average of 26 percent.

310. Between 2004 and 2007, total pacemaker cases at Tucson Heart Hospital declined from 283 to 226 cases, yet generator replacement procedures surged from 55 to 104 procedures.

311. In 2008, among 201 total pacemaker cases, 92 procedures were for generator replacements, representing 45.77 percent of the cases as compared to the national average of 28 percent.

312. The five-year rate of generator replacements as a percent of pacemaker cases at Tucson Heart Hospital was 35.8 percent as compared to the national average of 20.2 percent.

Northwest Medical Center and Tucson Medical Center

313. Within the same Tucson CBSA, Northwest Medical Center experienced replacement rates in excess of one standard deviation over the cohort average in 2004, 2005, and 2006.

314. Northwest Medical Center had 114 total pacemaker cases in 2004. Among these 114 cases, 29 procedures were for generator replacements in

pacemakers, representing 22 percent of cases as compared to the national average of 12.59 percent.

315. In 2005, among 129 total pacemaker cases, 48 procedures were for generator replacements, representing 37.21 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

316. In 2006, among 98 total pacemaker cases, 37 procedures were for generator replacements, representing 37.76 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

317. In 2007, among 108 total pacemaker cases, 36 procedures were for generator replacements, representing 33.33 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent.

318. In 2008, among 87 total pacemaker cases, 27 procedures were for generator replacements, representing 31.03 percent of the cases.

319. The five-year rate of generator replacements as a percent of pacemaker cases at Northwest Medical Center was 32.28 percent as compared to the national average of 20.2 percent.

Tucson Medical Center

320. In the same Tucson CBSA, Tucson Medical Center experienced generator replacement rates in excess of one standard deviation in 2006. The replacement rates at Tucson Medical Center moved from 21.32 percent of total cases in 2004 to 22.94 percent of total cases in 2005, 38.46 percent in 2006, and 35.56 percent in 2007.

Additional Clusters Appear in CBSAs Located in Close Proximity to Each Other Within State Regions

Cluster Ten in CBSAs Located in Central Coast California

321. Additional clusters appear in CBSAs located in close proximity to each other within state regions. Such a cluster emerges in coastal central California where four hospitals have repeatedly experienced replacement rates in excess of one or two standard deviations beyond cohort averages.

Santa Rosa Medical Center

322. In 2004 at Santa Rosa Medical Center, there were 236 total pacemaker cases. Among these 236 total cases, there were 36 generator replacement procedures, representing 16.12 percent of the total cases.

323. In 2005 at Santa Rosa Medical Center, there were 212 total pacemaker cases. Among these 212 total cases, there were 69 generator replacement procedures, representing 32.55 percent of the total cases. In single year total cases declined from 236 to 216, yet generator replacement procedures nearly doubled in number from 36 procedures in 2004 to 69 procedures to 2005.

324. In 2006 at Santa Rosa Medical Center, there were 225 total pacemaker cases. Among these 225 total cases, there were 80 generator replacement procedures, representing 35.56 percent of the total cases.

325. In 2007 at Santa Rosa Medical Center, there were 198 total pacemaker cases. Among these 198 total cases, there were 90 generator replacement procedures, representing 45.45 percent of the cases.

326. In 2008 at Santa Rosa Medical Center, there were 176 total pacemaker cases. Among these 176 total cases, there were 74 generator replacement procedures, representing 42.05 percent of the cases.

327. Between 2004 and 2007, total cases declined from 236 to 198; however, generator replacement procedures nearly tripled in number. Between 2004 and 2007, generator replacement procedures moved from 16.12 percent of cases in 2004 to 45.45 percent of cases in 2007.

Saint Helena Hospital

328. In 2004 at Saint Helena Hospital, there were 166 total pacemaker cases. Among these 166 total cases, there were 30 generator replacement procedures, representing 16.07 percent of the total cases.

329. In 2005 at Saint Helena Hospital, there were 108 total pacemaker cases. Among these 108 total cases, there were 25 generator replacement procedures, representing 23.05 percent of the total cases.

330. In 2006 at Saint Helena Hospital, there were 121 total pacemaker cases. Among these 121 total cases, there were 39 generator replacement procedures, representing 32.23 percent of the total cases.

331. In 2007 at Saint Helena Hospital, there were 119 total pacemaker cases. Among these 119 total cases, there were 53 generator replacement procedures, representing 44.54 percent of the cases.

332. Between 2004 and 2007, generator replacement procedures jumped from 16.02 percent of total cases in 2004 to 44.54 percent of total cases in 2007. Between 2004 and 2007, while total cases declined from 166 cases in 2004 to 119 cases in 2007, generator replacement procedures surged from 30 procedures in 2004 to 53 procedures in 2007.

333. In 2008 at Saint Helena Hospital, there were 121 total pacemaker cases. Among these 121 total cases, there were 43 generator replacement procedures, representing 35.54 percent of the cases.

O'Connor Hospital

334. In 2004 at O'Connor Hospital, there were 100 total pacemaker cases. Among these 100 total cases, there were 14 generator replacement procedures, representing 14 percent of the total cases.

335. In 2005 at O'Connor Hospital, there were 99 total pacemaker cases. Among these 99 total cases, there were 27 generator replacement procedures, representing 27.27 percent of the total cases.

336. In 2006 at O'Connor Hospital, there were 139 total pacemaker cases. Among these 139 total cases, there were 38 generator replacement procedures, representing 27.34 percent of the total cases.

337. In 2007 at O'Connor Hospital, there were 140 total pacemaker cases. Among these 140 total cases, there were 64 generator replacement procedures, representing 45.71 percent of the cases.

338. In 2008 at O'Connor Hospital, there were 120 total pacemaker cases. Among these 120 total cases, there were 40 generator replacement procedures, representing 33.33 percent of the cases.

339. Between 2004 and 2007, generator replacement procedures moved from 14 percent of cases in 2004 to 45.71 percent of cases in 2007.

340. Between 2004 and 2007, generator replacement procedures jumped from 14 procedures in 2004 to 64 procedures in 2007. Generator replacement procedures grew by 450 percent while total cases grew by only 40 percent.

Salinas Valley Memorial Hospital

341. Within the same vicinity in central coastal California, at Salinas Valley Memorial Hospital, there were 212 total pacemaker cases in 2004. Among these 212 total cases, there were 42 generator replacement procedures, representing 19.81 percent of the total cases.

342. In 2005 at Salinas Valley Memorial Hospital, there were 185 total pacemaker cases. Among these 185 total cases, there were 35 generator replacement procedures, representing 18.92 percent of the total cases.

343. In 2006 at Salinas Valley Memorial Hospital, there were 158 total pacemaker cases. Among these 158 total cases, there were 59 generator replacement procedures, representing 37.34 percent of the total cases.

344. In 2007 at Salinas Valley Memorial Hospital, there were 157 total pacemaker cases. Among these 157 total cases, there were 55 generator replacement procedures, representing 35.03 percent of the cases.

345. In 2008 at Santa Rosa Medical Center, there were 186 total pacemaker cases. Among these 186 total cases, there were 93 generator replacement procedures, representing 50 percent of the cases.

346. Between 2004 and 2008, generator replacement procedures moved from 19.18 percent of total cases in 2004 to 50 percent of total cases in 2008. Between 2004 and 2008, total cases declined slightly from 212 cases in 2004 to 186 cases in 2008. Yet generator replacement procedures surged from 42 procedures in 2004 to 93 procedures in 2008.

Cluster Eleven in Mississippi

347. Another cluster appears in Mississippi. Forrest General Hospital in Hattiesburg, Mississippi repeatedly experienced replacement rates in excess of one standard deviation beyond the cohort average in 2005, 2006, 2007, and 2008.

348. In close proximity to Forrest General is Baptist Memorial Hospital---North Mississippi. In 2007 and 2008, Baptist Memorial Hospital-North Mississippi experienced replacement rates in excess of 2 standard deviations beyond the cohort average. In 2006, the replacement rates at Baptist Memorial Hospital exceeded one standard deviation beyond the cohort average.

Forrest General Hospital, Mississippi

349. Between 2004 and 2008, generator replacement rates at Forest General moved from 13.59 percent of total cases in 2004 to 32.64 percent in 2005, 37.22 percent in 2006, 38.95 percent in 2007, and 48.17 percent in 2008.

350. Between 2004 and 2008 total annual pacemaker cases remained stable with an average 192 cases per year. Yet replacement procedures at Forrest General Hospital surged from 28 procedures in 2004 to 92 procedures in 2008.

351. In 2004, Forrest General Hospital had 206 total pacemaker cases. Among these 206 cases, 28 procedures were for generator replacements in pacemakers, representing 13.59 percent of cases which was close to the national average of 12.59 percent among all hospitals.

352. In 2005, among 193 total pacemaker cases, 63 procedures were for generator replacements, representing 32.64 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

353. In 2006, among 180 total pacemaker cases, 67 procedures were for generator replacements, representing 37.22 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

354. In 2007, among 190 total pacemaker cases, 74 procedures were for generator replacements, representing 38.95 percent of the cases as compared to the national average of 26 percent.

355. In 2008, among 191 total pacemaker cases, 92 procedures were for generator replacements, representing 48.17 percent of the cases as compared to the national average of 28 percent.

356. Between 2004 and 2008, total pacemaker cases at Forrest General declined from 206 to 191 cases, yet replacement procedures surged from 28 to 92 procedures.

357. The five-year rate of generator replacements as a percent of pacemaker cases at Forrest General Hospital was 33.8 percent as compared to the national average of 20.2 percent.

Baptist Memorial Hospital North Mississippi

358. In 2004, Baptist Memorial Hospital had 165 total pacemaker cases. Among these 165 cases, only 5 procedures were for generator replacements in pacemakers, representing 3 percent of cases which was below the national average of 12.59 percent among all hospitals.

359. In 2005, among 68 total pacemaker cases, only 1 procedure was for a generator replacement, representing 1.4 percent of the cases.

360. In 2006, among 59 total pacemaker cases, 22 procedures were for generator replacements, representing 37.29 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

361. In 2007, among 107 total pacemaker cases, 55 procedures were for generator replacements, representing 51.40 percent of the cases as compared to the national average of 26 percent.

362. In 2008, among 114 total pacemaker cases, 56 procedures were for generator replacements, representing 49.12 percent of the cases as compared to the national average of 28 percent.

363. Comparing 2004 and 2008, total pacemaker cases at Baptist Memorial Hospital declined from 165 cases in 2004 to 114 cases in 2008, yet replacement procedures surged from 5 procedures in 2004 to 56 procedures in 2008.

364. Between 2004 and 2008, the generator replacement rate at Baptist Memorial moved from 3 percent of total cases in 2004 to 49 percent of total cases in 2008.

Saint Dominic-Jackson Memorial Hospital

365. Another Mississippi location provides further evidence of the cluster. Although replacement rates at Saint Dominic-Jackson Memorial Hospital exceeded one standard deviation in only one of the five years (2007), the jumps in replacement rates are significant.

366. In 2004, Saint Dominic had 160 total pacemaker cases. Among these 160 cases, only 7 procedures were for generator replacements in pacemakers, representing 4.38 percent of cases.

367. In 2005, among 97 total pacemaker cases, there were 22 generator replacements, representing 22.68 percent of the cases.

368. In 2006, among 98 total pacemaker cases, 11 procedures were for generator replacements, representing 11.22 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

369. Yet in 2007, among 127 total pacemaker cases, 49 procedures were for generator replacements, representing 38.58 percent of the cases. Between 2004 and 2007, replacement procedure rates at Saint Dominic moved from 4.38 to 38.58 percent of total cases. Comparing 2004 and 2007, total pacemaker cases declined from 160 cases in 2004 to 127 cases in 2007. Yet generator replacement procedures surged from 7 procedures in 2004 to 49 procedures in 2007.

Cluster Twelve on Nebraska/Iowa Border

370. In close proximity but in different CBSAs, two facilities on the Iowa-Nebraska border have repeatedly experienced replacement rates in excess of one or two standard deviations over the cohort average.

Creighton University Medical Center

371. The replacement rates at Creighton University Medical Center exceeded two standard deviations in 2004 and exceeded one standard deviation in 2005 and 2006.

372. Creighton University Medical Center had 221 total pacemaker cases in 2004. Among these 221 cases, 64 procedures were for generator replacements, representing 29 percent of cases as compared to the national average of 12.59 percent among all hospitals.

373. In 2005, among 184 total pacemaker cases, 65 procedures were for generator replacements, representing 35.33 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

374. In 2006, among 118 total pacemaker cases, 39 procedures were for generator replacements, representing 33.05 percent of the cases. The national

average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

375. The five rate of generator replacement procedures as a percent of pacemaker cases at Creighton was 31.4 percent as compared to the national average of 20.2 percent.

Mercy Medical Center---Sioux City, Iowa

376. In close proximity, Mercy Medical had 148 total pacemaker cases in 2004. Among these 148 cases, 41 procedures were for generator replacements in pacemakers, representing 28 percent of cases as compared to the national average of 12.59 percent

377. In 2005, among 128 total pacemaker cases, 49 procedures were for generator replacements, representing 38.28 percent of the cases or over double the national average of 18 percent.

378. In 2006, among 119 total pacemaker cases, 41 procedures were for generator replacements, representing 34.45 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

379. In 2007, among 91 total pacemaker cases, 27 procedures were for generator replacements, representing 29.67 percent of the cases.

380. In 2008, among 83 total pacemaker cases, 29 procedures were for generator replacements, representing 34.94 percent of the cases.

381. The five-year rate of generator replacements as a percent of pacemaker cases at Mercy Medical was 32.9 percent as compared to the national average of 20.2 percent.

Cluster Thirteen in Central and South Georgia at Multiple Hospitals

382. Six Georgia hospitals in central and south Georgia have repeatedly experienced replacement rates in excess of one or two standard deviations over cohort averages.

383. Saint Francis Hospital in Columbus experienced replacement rates in excess of one standard deviation in 2004 and in excess of two standard deviations in 2005. Medical Center of Central Georgia experienced replacement rates which exceeded one standard deviation in 2004, 2005, and 2006. In close proximity, South Georgia Medical Center had replacement rates which exceeded one standard deviation in 2007 and two standard deviations in 2008. University Hospital in Augusta had replacement rates which exceeded one standard deviation in 2004, 2005, and 2006. Southeast Georgia Health System had replacement rates in excess of two standard deviations in 2005 and

in excess of one standard deviation in 2008. In 2005 and 2006, St. Joseph's Hospital in Savannah experienced replacement rates in one standard deviation.

384. The detailed data from these six Georgia hospitals reveal striking jumps in replacement rates. For example, Medical Center of Central Georgia had 499 total pacemaker cases in 2004. Among these 499 cases, at least 112 procedures were for generator replacements in pacemakers, representing 22 percent of cases as compared to the national average of 12.59 percent.

385. In 2005, among 448 total pacemaker cases, 162 procedures were for generator replacements, representing 36.16 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

386. In 2006, among 516 total pacemaker cases, 180 procedures were for generator replacements, representing 34.88 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent. Between 2005 and 2006, the rate of generator replacement growth at Medical Center of Central Georgia was over double the national average.

387. Total pacemaker cases at Medical Center of Central Georgia moved from 499 to 516 cases between 2004 and 2006. Yet replacement procedures jumped from 112 to 180 procedures.

388. The five-year total of generator replacements as a percent of pacemaker cases at Medical Center of Central Georgia was 31.2 percent as compared to the national average of 20.2 percent.

389. South of Medical Center of Central Georgia in Valdosta, Georgia, South Georgia Medical Center experienced generator replacement rates which moved from 15.98 percent of total pacemaker cases in 2004 to 39.05 percent of total pacemaker cases in 2007 to 63.64 percent of total pacemaker cases in 2008.

390. At Saint Francis Hospital in Columbus, Georgia, replacement rates moved from 25.42 percent of pacemaker cases to 46.21 percent of cases in a single year between 2004 and 2005.

391. In 2004, there were 118 total pacemaker cases at Saint Francis Hospital. Among these 118 total cases, 30 procedures were for generator replacements, representing 25.42 of total cases which was double the national average of 12.59 percent.

392. In 2005, there were 195 total pacemaker cases. Among these 195 total cases, there were 94 generator replacement procedures which represented 46.21 percent of total cases as compared to the national average of 18 percent.

Cluster Fourteen in Chattanooga Vicinity

393. Mr. Stokes' investigation and analyses reveal a cluster in the Chattanooga vicinity with three facilities repeatedly experiencing replacement rates in excess of one or two standard deviations over the cohort averages.

Redmond Regional Medical Center

394. Replacement rates at Redmond Regional Medical Center (in Northwest Georgia near Chattanooga) exceeded one standard deviation over the national cohort average in 2004, 2005, 2006, and 2008. And in 2007, replacement rates at Redmond Regional exceeded two standard deviations over the national cohort average.

395. For example, Redmond Regional had 248 total pacemaker cases in 2004. Among these 248 cases, 54 procedures were for generator replacements in pacemakers, representing 21.77 percent of cases as compared to the national average of 12.59 percent.

396. In 2005, among 188 total pacemaker cases, 68 procedures were for generator replacements, representing 36.17 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

397. In 2006, among 208 total pacemaker cases, 65 procedures were for generator replacements, representing 31.25 percent of the cases. The national

average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

398. In 2007, among 204 total pacemaker cases, 94 procedures were for generator replacements, representing 46.08 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2007 was 26 percent

399. In 2008, among 218 total pacemaker cases, 102 procedures were for generator replacements, representing 46.79 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2008 was 28 percent.

400. Between 2004 and 2008, total pacemaker cases at Redmond Regional declined from 248 to 218 cases, yet generator replacement procedures nearly doubled from 54 to 102 procedures.

401. Replacement rate percents at Redmond Regional surged from 21.77 percent of total cases in 2004 to 46.08 percent of total cases in 2007 and 46.79 percent of total cases in 2008.

Memorial Hospital

402. At Memorial Hospital in Chattanooga, generator replacement rates moved from 21.30 percent of total pacemaker cases in 2004 to 43.20 percent of total pacemaker cases in 2008.

403. In 2004, there were 324 total pacemaker cases. Among these 324 cases, there were 69 generator replacement procedures at Memorial Hospital. In 2008, there were 294 total pacemaker cases. Among these 294 cases, there were 127 generator replacement procedures at Memorial Hospital. While total pacemaker implant cases declined from 324 cases in 2004 to 294 cases in 2008, generator replacement procedures nearly doubled over this five-year period, moving from 69 to 127 procedures.

Huntsville Hospital

404. Close to Memorial Hospital in Chattanooga and Redmond Regional Medical Center in Rome, Georgia is Huntsville Hospital where replacement rates moved from 8.03 percent of total pacemaker cases in 2004 to 44.06 percent of total pacemaker cases in 2008.

405. In 2004 there were 436 pacemaker cases. Among these 436 pacemaker cases, there were 35 generator replacement procedures at Huntsville Hospital, representing 8.03 percent of the total cases.

406. In 2005 there were 271 total pacemaker cases with only 30 generator replacement procedures at Huntsville Hospital, representing 11.07 percent of the total cases.

407. In 2006 there were 396 total pacemaker cases with 90 generator replacement procedures at Huntsville Hospital, representing 22.73 percent of the total cases.

408. In 2007 there were 409 total pacemaker cases, including 155 generator replacement procedures at Huntsville Hospital. These generator replacement procedures represented 37.90 percent of the total cases.

409. In 2008 there were 404 total pacemaker cases, including 178 generator replacement procedures at Huntsville Hospital.

410. Comparing 2004 and 2008, total pacemaker cases declined slightly moving from 436 cases in 2004 to 404 cases in 2008. Yet generator replacement procedures surged from 35 procedures in 2004 to 178 procedures in 2008.

Cluster Fifteen in Dallas-Paris Texas Region

411. A cluster emerges also in the Dallas region and the neighboring town of Paris, Texas approximately 100 miles away.

Paris Regional Medical Center

412. In 2006, the replacement rates at Paris Regional exceeded one standard deviation over the cohort average among hospitals with at least 500 pacemaker cases over the time period 2004-2008 discussed below. In 2008, the replacement rates at Paris Regional exceeded two standard deviations over the national cohort average.

413. For example, Paris Regional had 271 total pacemaker cases in 2004. Among these 271 cases, 56 procedures were for generator replacements in pacemakers, representing 21 percent of cases as compared to the national average of 12.59 percent among all hospitals.

414. In 2005, among 151 total pacemaker cases, 33 procedures were for generator replacements, representing 21.85 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

415. In 2006, among 126 total pacemaker cases at Paris Regional, 47 procedures were for generator replacements, representing 37.30 percent of the cases while the national average of generator replacements as a percent of total pacemaker cases in 2006 which was 20 percent. Between 2005 and 2006, Paris Regional experienced generator replacement growth at the rate of 42 percent while the national average among all hospitals was minus 1 percent.

416. In 2007, among 113 total pacemaker cases at Paris Regional, 37 procedures were for generator replacements, representing 32.74 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases among all hospitals in 2007 was 26 percent.

417. Yet in 2008, among 95 total pacemaker cases at Paris Regional, 49 procedures were for generator replacements, representing 51.58 percent of the cases as compared to the national average of 28.10 percent.

418. Between 2004 and 2008, generator replacement procedures at Paris Regional moved from 21 percent of total pacemaker cases in 2004 to 51.58 percent of total pacemaker cases in 2008.

419. Between 2004 and 2008, total pacemaker cases declined drastically at Paris Regional, moving from 271 cases in 2004 to 95 cases in 2008. Yet generator replacement procedures only moved from 56 to 49 procedures.

Baylor Jack and Jane Hamilton Heart and Vascular Hospital

420. In close proximity to Paris Regional is Baylor Jack and Jane Hamilton Heart and Vascular Hospital.

421. Replacement rates at Baylor Jack and Jane Hamilton Heart and Vascular Hospital exceeded one standard deviation for five consecutive years in 2004, 2005, 2006, 2007, and 2008.

422. For example, Baylor Jack and Jane Hamilton Heart and Vascular Hospital had 308 total pacemaker cases in 2004. Among these 308 cases, 74 procedures were for generator replacements in pacemakers, representing 24.03 percent of cases as compared to the national average of 12.59 percent among all hospitals.

423. In 2005, among 313 total pacemaker cases, 96 procedures were for generator replacements, representing 30.67 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

424. In 2006, among 323 total pacemaker cases at Baylor Jack and Jane Hamilton Heart and Vascular Hospital, 119 procedures were for generator replacements, representing 36.84 percent of the cases while the national average of generator replacements as a percent of total pacemaker cases in 2006 which was 20 percent.

425. In 2007, among 302 total pacemaker cases at Baylor Jack and Jane Hamilton Heart and Vascular Hospital, 118 procedures were for generator replacements, representing 39.07 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases among all hospitals in 2007 was 26 percent.

426. In 2008, among 303 total pacemaker cases, 122 procedures were for generator replacements, representing 40.26 percent of the cases as compared to the national average of 28.10 percent.

427. Between 2004 and 2008, total pacemaker cases remained stable at 308 and 303 cases respectively. Yet generator replacement procedures surged from 74 procedures in 2004 to 122 procedures in 2008.

428. The five-year replacement rate percent at Baylor Jack and Jane Hamilton Heart and Vascular Hospital was 34.15 percent as compared to the national average of 20.2 percent.

Cluster Sixteen in the Arkansas Region

429. Another regional cluster appears in Arkansas. In 2007 and 2008, Arkansas Heart Hospital experienced replacement rates in excess of one standard deviation beyond the cohort average. In 2007, the replacement rates at Baxter Regional Medical Center exceeded two standard deviations beyond the cohort average. In 2004 and 2005, replacement rates at St. Edward Mercy Medical Center exceeded one standard deviation beyond the cohort average.

Arkansas Heart Hospital

430. In 2004, Arkansas Heart Hospital had 333 total pacemaker cases. Among these 333 cases, 71 procedures were for generator replacements in

pacemakers, representing 21.32 percent of cases as compared to the national average of 12.59 percent among all hospitals.

431. In 2005, among 256 total pacemaker cases, 65 procedures were for generator replacements, representing 25.39 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

432. In 2006, among 306 total pacemaker cases, 75 procedures were for generator replacements, representing 24.51 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

433. In 2007, among 315 total pacemaker cases, 121 procedures were for generator replacements, representing 38.41 percent of the cases as compared to the national average of 26 percent. In a single year, generator replacement procedures jumped from 75 procedures to 121 procedures while total pacemaker cases remained stable.

434. In 2008, among 341 total pacemaker cases, 140 procedures were for generator replacements, representing 41.06 percent of the cases as compared to the national average of 28 percent.

435. Over the five-year period, total pacemaker cases at Arkansas Heart Hospital remained stable, while replacement procedures doubled. Between

2004 and 2008, generator replacement procedures moved from 21.32 percent of total cases to 41.06 percent of total cases. In 2004, among 333 total pacemaker cases, there were 71 generator replacements. In 2008, among 341 total pacemaker cases, there were 140 generator replacements.

Baxter Regional Medical Center-Arkansas

436. In 2004, Baxter Regional Medical Center had 129 total pacemaker cases. Among these 129 cases, only 4 procedures were for generator replacements in pacemakers, representing 3.10 percent of total pacemaker cases.

437. In 2005, among 110 total pacemaker cases, 19 procedures were for generator replacements, representing 17.27 percent of the cases as compared to the national average of 18 percent.

438. In 2006, among 132 total pacemaker cases, 32 procedures were for generator replacements, representing 24.24 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

439. Yet in 2007, among 128 total pacemaker cases, 61 procedures were for generator replacements, representing 47.66 percent of the cases as compared to the national average of 26 percent.

440. In a single year, generator replacement procedures doubled while total cases remained stable. Between 2004 and 2007, total pacemaker cases remained stable, while generator replacement procedures escalated from 4 replacement procedures in 2004 to 61 replacement procedures in 2007.

Cluster Seventeen in West Virginia

441. Another regional cluster appears in West Virginia. In 2006 and 2007, Charleston Area Medical Center experienced replacement rates in excess of one standard deviation beyond the cohort average. In 2004, 2006, and 2007, the replacement rates at King's Daughters Medical Center exceeded one standard deviation beyond the cohort average.

Charleston Area Medical Center

442. For example, in 2004, Charleston Area Medical Center had 342 total pacemaker cases. Among these 342 cases, only 31 procedures were for generator replacements in pacemakers, representing 9.06 percent of total pacemaker cases.

443. In 2005, among 388 total pacemaker cases, 74 procedures were for generator replacements, representing 19.07 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

444. In 2006, among 487 total pacemaker cases, 166 procedures were for generator replacements, representing 34.09 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

445. In 2007, among 418 total pacemaker cases, 161 procedures were for generator replacements, representing 38.52 percent of the cases as compared to the national average of 26 percent.

446. In 2008, among 358 total pacemaker cases, 127 procedures were for generator replacements, representing 35.47 percent of the cases as compared to the national average of 28 percent.

447. Over the five-year period, generator replacement procedures at Charleston Area Medical Center jumped from 9 percent of total pacemaker cases in 2004 to nearly 35 percent in 2006, 38 percent in 2007, and 35 percent in 2008.

448. Between 2004 and 2008, total pacemaker cases remained stable at 342 in 2004 and 358 cases in 2008. Yet generator replacement procedures soared from 31 procedures in 2004 to 127 procedures in 2008.

Cluster Eighteen in Connecticut Region

449. Another regional cluster appears in the Connecticut region with three hospitals experiencing replacement rates repeatedly in excess of one or two standard deviations over the cohort average. In 2004, 2005, 2006, 2007, and 2008, Binghamton General Hospital experienced replacement rates in excess of one standard deviation beyond the cohort average. In 2006 and 2008, the replacement rates at Vassar Brother Medical Center exceeded one standard deviation beyond the cohort average and exceeded two standard deviations in 2007. In 2004, 2005, 2007, and 2008, replacement rates at Hospital of Saint Raphael exceeded one standard deviation.

Vassar Brothers Medical Center

450. For example, in 2004, Vassar Brothers Medical Center had 126 total pacemaker cases. Among these 126 cases, only 4 procedures were for generator replacements in pacemakers, representing 3.17 percent of cases.

451. In 2005, among 117 total pacemaker cases, only 11 procedures were for generator replacements, representing 9.40 percent of the cases.

452. In 2006, among 151 total pacemaker cases, 47 procedures were for generator replacements, representing 31.13 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2006 was 20 percent.

453. In a two-year period from 2004 to 2006, the replacement rates at Vassar Brothers Medical Center moved from 3.17 percent to 31.13 percent of total cases.

454. In 2007, among 155 total pacemaker cases, 70 procedures were for generator replacements, representing 46.16 percent of the cases as compared to the national average of 26 percent.

455. In a three-year period from 2004 to 2007, the replacement rates at Vassar Brothers Medical Center moved from 3.17 percent to 46.16 percent of total cases.

456. In 2008, among 137 total pacemaker cases, 56 procedures were for generator replacements, representing 40.88 percent of the cases as compared to the national average of 28 percent.

Binghamton General Hospital

457. In close proximity to Vassar Brothers Medical Center, Binghamton General Hospital experienced replacement rates in excess of one standard deviation for five consecutive years, 2004-2008.

458. Binghamton General Hospital had 203 total pacemaker cases in 2004. Among these 203 cases, 49 procedures were for generator replacements in

pacemakers, representing 24.14 percent of cases as compared to the national average of 12.59 percent among all hospitals.

459. In 2005, among 168 total pacemaker cases, 52 procedures were for generator replacements, representing 30.95 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases in 2005 was 18 percent.

460. In 2006, among 147 total pacemaker cases at Binghamton General Hospital, 46 procedures were for generator replacements, representing 31.29 percent of the cases while the national average of generator replacements as a percent of total pacemaker cases in 2006 which was 20 percent.

461. In 2007, among 134 total pacemaker cases at Binghamton General Hospital, 54 procedures were for generator replacements, representing 40.30 percent of the cases. The national average of generator replacements as a percent of total pacemaker cases among all hospitals in 2007 was 26 percent.

462. In 2008, among 151 total pacemaker cases, 70 procedures were for generator replacements, representing 46.36 percent of the cases as compared to the national average of 28.10 percent.

463. Between 2004 and 2008, generator replacement procedures moved from 24.14 percent to 46.36 percent of total pacemaker cases at Binghamton General Hospital.

464. Between 2004 and 2008, total pacemaker cases declined from 203 in 2004 to 151 cases in 2008. Yet generator replacement procedures increased from 49 procedures in 2004 to 70 procedures in 2008.

465. The five-year replacement rate percent at Binghamton General Hospital was 33.75 percent as compared to the national average of 20.2 percent.

The Defendants Have Concealed the Problem

466. The major escalation in generator replacement procedures occurred in the same time period that the Defendants touted the longevity of their devices and reported minimal generator replacement procedures needed for their products.

467. The Defendants purport to have policies in place which require the return, evaluation, and testing of all explanted devices. The allied professionals employed by the Defendants are typically responsible for facilitating the return of explanted devices to their employers for evaluation and investigation of potential malfunction, including premature generator depletion.

468. The Defendants each have represented to the FDA and physicians that they have effective and enforced programs and policies in place to recover and evaluate explanted devices for potential malfunction, including premature generator depletion. In fact, they don't.

469. The Defendants are aware of the escalation in generator replacement procedures over the last 6 years. They are also aware that the vast majority of these explanted devices are never returned by their sales agents to the company for evaluation of malfunction, including evaluation of potential premature generator depletion.

470. Each year Defendants publish Product Performance Reports which purport to contain "important patient management information for physicians."

471. In 2010, the three Defendants' Product Performance Reports collectively reported 3,413,013 pacemakers implanted and registered in the United States dating back to 1989. According to the Defendants' 2010 Product Performance Reports, only 554 of such 3.4 million pacemakers have experienced suspected or confirmed premature generator depletion. This number represents .02 percent of all pacemakers implanted in the United States.

472. The Defendants closely track every pacemaker procedure and every generator replacement procedure at every hospital by every employed sales representative in the United States. The Defendants' employed allied professionals handle programming of each of their pacemakers after each implantation. Yet the three Defendants collectively report only 554 "confirmed

or suspected cases of premature generator depletion" in the entire history of their 3.4 million pacemaker products in the United States.

473. Boston Scientific does not even report "confirmed cases of generator depletion." Rather, Boston Scientific simply lists "unconfirmed reports of early generator depletion" and claims that out of its 707,000 pacemaker products implanted in the United States, there were 524 cases of "unconfirmed premature generator depletion."

474. In its 2010 Product Performance Report, Medtronic claims that among its 1,879,300 pacemakers implanted in the United States, there are only 559 cases of "malfunction with or without compromised therapy" which includes "suspected premature generator depletion." These 559 cases represent .03 percent of all Medtronic pacemakers in the United States. Medtronic does not report confirmed cases of "premature generator depletion."

475. In its 2010 Product Performance Report, St. Jude claims among its 826,713 pacemakers implanted in the United States, there have been only 30 cases of "premature generator replacement." St. Jude does not report the number of "normal generator depletions" among its 826,713 pacemaker products implanted in the United States.

476. The Defendants know that there are thousands of cases of premature pacemaker generator depletion which they are deliberately not reporting.

477. The Defendants' representations and product performance reports are at odds with the major escalation in generator replacement procedures among Medicare patients between 2004 and 2008.

478. Defendants have disguised the problem of premature generator depletion through a scheme which defines generator depletion without considering whether the output settings were appropriately programmed. The Defendants' definition of premature depletion is designed to not reveal or identify the problem of output settings.

479. Medtronic's Product Performance Report defines "normal generator depletion" as "the condition when…a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information." Neither definition contemplates consideration of the appropriate output settings or expected longevity with the appropriate output settings. Rather, the definition contemplates 50 percent predicted longevity at the default settings or 80 percent predicted longevity "calculated using the available device setting information."

480. Boston Scientific's Product Performance Report contains a similar definition of "normal generator depletion." Boston Scientific has represented to physicians and the FDA that it "performs generator usage analysis, including generator status verification, on all devices returned without a complaint." For explanted pacemakers which are not returned to Boston Scientific, Boston Scientific automatically classifies such pacemakers as "normal generator depletions" despite the fact that it knows the exact longevity of the device and the exact output settings.

481. Medtronic's Product Performance Reports recognizes only a "fraction" of explanted pacemakers are returned for testing. Medtronic's Cardiac Rhythm Disease Management purportedly "uses both returned product analysis and multicenter clinical studies to monitor performance."

482. While it touts its program to monitor pacemaker device performance "using an active multicenter clinical study," the reality is that Medtronic is under-reporting the incidence of premature generator depletion among its pacemaker products. Medtronic reports 1,879,300 registered pacemakers implanted in the United States. According to Medtronic's 2010 Product Performance Report, only 559 of such 1.87 million pacemakers or .03 percent have experienced "malfunction" which includes a category for "'suspected premature generator depletion."

483. While each Defendant purports to promote the importance of evaluating explanted devices, the Defendants know that their programs to evaluate explanted devices for premature generator depletion are ineffective because (1) they do not enforce return policies among sales representatives and the vast majority of explanted devices are never returned, and (2) they do not report generator longevity testing which evaluates or considers the appropriateness of output settings. Consequently, sales representatives know that their conduct to program devices at high output settings will escape classification as "premature generator depletions" under the Defendants' programs.

484. Although the Defendants claim that they inform regulatory bodies of each significant event that poses potential risk to patient health, the Defendants' conduct has caused a major under-reporting of premature generator depletions to physicians, the FDA, and the Medicare Program.

The Identification of the False Claims Caused by Defendants' Agents

485. The Defendants know the identity of false claims caused by their agents to the Medicare Program and such false claims may be determined from the Defendants' own records.

486. The respective Defendants closely track the incidence of generator replacement procedures associated with each employed sales representative. The respective Defendants track the incidence of generator replacements at each hospital where their allied professionals are marketing and programming pacemaker devices.

487. The Defendants know the number of generator replacement procedures each month and they know the identity of each respective employed sales agent or allied professional involved in the programming of each particular device where a generator was depleted.

488. For each pacemaker, Defendants have written records of the pacemaker's programmed settings, including the voltage output settings. The programmed settings are also stored on the computerized hard drive within the pacemaker generator.

489. Defendants closely monitor and track their sales representatives by numbers of generator replacement procedures each quarter of the fiscal year. They closely monitor and track revenues associated with each generator replacement for devices programmed by each sales representative at every hospital in the United States.

490. The Defendants know the expected longevity of every generator based on the voltage output settings of the generator.

491. For example, the Medtronic EnPulse DR series, including models E1DRO1, E1DR03, and E1DR06, has a generator longevity range of 4.4 years at the high 5.0 volt setting to 7.5 years at the low 2.5 volt setting. The Kappa 700 DR, including models KDR701, KDR703, and KDR706, have a generator longevity range of 3.0 years at the high 5.0 volt setting to 5.5 years at the low 2.5 volt setting.

492. Each pacemaker generator manufactured by each Defendant has a significant wide range in longevity depending on the output settings. The respective Defendants and their agents know the exact longevity ranges and associated output settings in detail for each pacemaker model.

493. If the Defendants did not receive the explanted device after a generator replacement to evaluate the output settings on the generator computer, they still know the voltage of output settings based on records of each time the devices was programmed by their agents. They may also back-calculate the output settings based on the generator longevity and their own detailed knowledge of precise longevity times associated with particular voltage settings.

The False Claims Act

494. The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729 (a) (1), as added by subsection (a) (1) shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. § 3729) that are pending on or after date…" FERA, § 4(f). The conduct in this Complaint occurred from at least 2004 through the present, this Complaint will predominantly reference pre-FERA numbering for paragraphs 3729(a) of the FCA with the limited exception of referencing the post-FERA numbering, pursuant to § 4(f) for conduct on or after June 7, 2008 when Defendants "knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim…" 31 U.S.C. § 3729 (a)(1)(B).

495. Under the pre-FERA and post-FERA False Claims Act, "'knowing' and 'knowingly' mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 U.S.C. 3729 (b).

496. In considering the requisite scienter which subjects a defendant to liability under the False Claims Act, "no proof of specific intent to defraud is required." Under the False Claims Act, a defendant is liable for acting in "reckless disregard of the truth or falsity of the information" or acting in "deliberate ignorance of the truth or falsity of the information."

497. With respect to each claim at issue, the respective Defendant responsible for such claim either (1) had actual knowledge of the information; or (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud the United States is required under the False Claims Act.

Medicare's Conditions and Requirements for Payment

498. The Medicare Act, 42 U.S.C. 1395y (a) (1) (A), contains an express condition of payment---"no payment may be made [under the Medicare statute] for any expenses incurred which…are not reasonable and necessary for the diagnosis or treatment of illness or injury." The Medicare Act explicitly links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary."

499. A hospital's or physician's services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y (a) (i). A physician and hospital may not be reimbursed by Medicare for medically unnecessary services.

500. As a condition of payment of claims under the Medicare Program, health care providers must certify compliance with the Medicare Act Section 1395y (a) (1) (A) and certify that they were only seeking payment for services that were reasonable and necessary.

501. "Part B" of the Medicare Program covers certain facilities and medical services provided to qualified patients/beneficiaries on an outpatient basis. Part B of the Medicare Program is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the Federal Treasury. Eligible individuals who are age 65 or older, or disabled, may enroll in Part B to obtain benefits in return for payments of monthly premiums as established by HHS. However, payments under the Medicare Program are generally made directly to service providers such as physicians, rather than to the patient/beneficiary. This occurs when the physician accepts assignment of the right to payment from the beneficiary. In that case, the physician bills the Medicare Program.

502. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of Part B of the Medicare Program, CMS contracts with "carriers." 42 U.S.C. § 1395u. Carriers, typically insurance companies, are responsible for processing the payment of Part B claims to physicians on behalf of CMS. *Id.*

503. As a condition of participation in Medicare Part B Program, providers agree to be familiar with, and abide by, the Program's reimbursement policies.

504. To bill the Medicare Program, a physician provider must submit an electronic or hard-copy claim form called "CMS 1500" to the physician's designated carrier.

505. When the CMS 1500 is submitted, the physician certifies that the services in question were "medically indicated and necessary for the health of the patient."

506. Physicians wishing to submit the CMS 1500 electronically must first submit a provider enrollment form.

507. Regardless of whether the form is submitted in hard copy or electronically, the billing physician certified to the following language on the CMS 1500 form that was submitted to Medicare: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient . . . ."

508. A physician's and hospital's services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y (a) (i). A physician and hospital may not be reimbursed by Medicare for medically unnecessary services.

509. The United States has been damaged because the Defendants' agents have caused claims to be submitted to the United States for unnecessary and unreasonable excessive generator replacement procedures associated with premature generator depletions.

510. The Defendants profited unlawfully from unnecessary and unreasonable pacemaker generator replacement procedures on elderly patients in the Medicare Program.

511. In addition to violating Medicare laws, the Defendants' agents' premature depletion of pacemaker generator longevity presents a public health risk to Medicare beneficiaries.

512. Based on information and belief, the schemes of Defendants' agents to deplete generators prematurely continue through the present, causing ongoing substantial damages to the Medicare Program.

Count I---Causing Presentation and Payment of False Claims (31 U.S.C. §3729(A) (1))

513. Relator repeats and realleges the foregoing paragraphs as if fully set forth herein.

514. The Defendants caused to be presented false claims for payment or approval to Federal Health Care Programs with respect to pacemaker generator replacement procedures excluded from coverage.

515. By virtue of the false claims caused by the Defendants, the United States sustained damages and continues to be damaged. The United States is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Count II---Causing False Records or False Statements Material to False Claims Being Paid (31 U.S.C. §3729(A) (2))(31 U.S.C. §3729(A) (1) (B))

516. Relator repeats and realleges the foregoing Paragraphs as if fully set forth herein.

517. The Defendants knowingly caused to be made or used false records, false certifications, and false statements material to the payment of false claims. The Defendants' conduct resulted in false certifications and false

records being presented to the United States and false claims being paid or approved by the United States in Federal Health Care Programs.

518. By virtue of the false records or false statements caused by the Defendants, the United States sustained damages and continues to be damaged. The United States is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Count III---Conspiracy to Cause False Claims in Violation of 31 U.S.C. § 3729(A) (3)

519. Relator repeats and realleges each allegation contained in the paragraphs above as though fully set forth herein.

520. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

521. Through the acts described above, the Defendants, acting in concert with other contractors, agents, partners, and/or representatives, conspired to knowingly cause to be presented, false claims to the United States and knowingly caused to be made or used false records and statements, and omitting material facts, to get false claims paid or approved.

522. As a result, the United States was unaware of the false claims caused by

Defendants and the United States paid and continues to pay claims that would not be paid if the Defendants' unlawful conduct was known to the United States.

523. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

524. By virtue of Defendants' conspiracy to defraud the United States, the United States sustained damages and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Prayers for Relief

On behalf of the United States, Mr. Stokes requests judgment against Defendants in the amount of the United States' damages arising from false claims billed to Federal Healthcare Programs for unnecessary generator replacement procedures as discussed above, trebled as required by law, for such civil penalties as are required by law, for a qui tam relators' share as specified by 31 U.S.C. §3730, for attorneys fees, costs and expenses as provided by 31 U.S.C. §3730, and for all such further legal and equitable relief as may be just and proper.

JURY TRIAL IS HEREBY DEMANDED

Respectfully submitted this ___ of May, 2011,

_____

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(Pro hac vice motions to be submitted)

Certificate of Service

This is to certify that I have this day served a copy of the within and foregoing Qui Tam Relators' Complaint Under 31 U.S.C. §3729, Federal False Claims Act by CERTIFIED MAIL RETURN RECEIPT REQUESTED addressed as follows:

The Honorable Eric H. Holder, Jr.
Attorney General of the United States of America
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

The Honorable Ronald C. Machen, Jr.
United States Attorney for the District of Columbia
555 4th Street N.W.
Washington, D.C. 20530

Respectfully submitted this ___ of June, 2011,

_____
Harry Huge

CIVIL COVER SHEET

JS-44
(Rev. 2/11 DC)

1:11-1082 ESH

I (a) PLAINTIFFS

United States of America ex. rel Ben R. Stokes

88888

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

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DEFENDANTS

Boston Scientific, Medtronic, Inc., and St. Jude Medical, Inc.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT
(IN U.S. PLAINTIFF CASES ONLY) Natick, MA
NOTE IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

SEALED

Case: 1:11-cv-01082
Assigned To : Huvelle, Ellen S.
Assign. Date : 6/14/2011
Description: General Civil

JURY ACTION

II. BASIS OF JURISDICTION

(PLACE AN x IN ONE BOX ONLY)

- (1) 1 U S Government Plaintiff
- (3) 3 Federal Question (U S Government Not a Party)
- (2) 2 U S Government Defendant
- (4) 4 Diversity (Indicate Citizenship of Parties in item III)

III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!

	PTF	DFT		PTF	DFT
Citizen of this State	1	1	Incorporated or Principal Place of Business in This State	4	4
Citizen of Another State	2	2	Incorporated and Principal Place of Business in Another State	5	5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

A. *Antitrust*

- 410 Antitrust

B. *Personal Injury/ Malpractice*

- 310 Airplane
- 315 Airplane Product Liability
- 320 Assault, Libel & Slander
- 330 Federal Employers Liability
- 340 Marine
- 345 Marine Product Liability
- 350 Motor Vehicle
- 355 Motor Vehicle Product Liability
- 360 Other Personal Injury
- 362 Medical Malpractice
- 365 Product Liability
- 368 Asbestos Product Liability

C. *Administrative Agency Review*

- 151 Medicare Act

Social Security:
- 861 HIA ((1395ff)
- 862 Black Lung (923)
- 863 DIWC/DIWW (405(g)
- 864 SSID Title XVI
- 865 RSI (405(g)

Other Statutes
- 891 Agricultural Acts
- 892 Economic Stabilization Act
- 893 Environmental Matters
- 894 Energy Allocation Act
- 890 Other Statutory Actions (If Administrative Agency is Involved)

D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

E. *General Civil (Other)* OR **F. *Pro Se General Civil***

Real Property
- 210 Land Condemnation
- 220 Foreclosure
- 230 Rent, Lease & Ejectment
- 240 Torts to Land
- 245 Tort Product Liability
- 290 All Other Real Property

Personal Property
- 370 Other Fraud
- 371 Truth in Lending
- 380 Other Personal Property Damage
- 385 Property Damage Product Liability

Bankruptcy
- 422 Appeal 28 USC 158
- 423 Withdrawal 28 USC 157

Prisoner Petitions
- 535 Death Penalty
- 540 Mandamus & Other
- 550 Civil Rights
- 555 Prison Condition

Property Rights
- 820 Copyrights
- 830 Patent
- 840 Trademark

Federal Tax Suits
- 870 Taxes (US plaintiff or defendant
- 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- 610 Agriculture
- 620 Other Food &Drug
- 625 Drug Related Seizure of Property 21 USC 881
- 630 Liquor Laws
- 640 RR & Truck
- 650 Airline Regs
- 660 Occupational Safety/Health
- 690 Other

Other Statutes
- 400 State Reapportionment
- 430 Banks & Banking
- 450 Commerce/ICC Rates/etc.
- 460 Deportation
- 462 Naturalization Application
- 465 Other Immigration Actions
- 470 Racketeer Influenced & Corrupt Organizations
- 480 Consumer Credit
- 490 Cable/Satellite TV
- 810 Selective Service
- 850 Securities/Commodities/ Exchange
- 875 Customer Challenge 12 USC 3410
- 900 Appeal of fee determination under equal access to Justice
- 950 Constitutionality of State Statutes
- [X] 890 Other Statutory Actions (if not administrative agency review or Privacy Act

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus-General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus - Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/PRIVACY ACT* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loans (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 730 Labor/Mgmt. Reporting & Disclosure Act ☐ 740 Labor Railway Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 444 Welfare ☐ 440 Other Civil Rights ☐ 445 American w/Disabilities-Employment ☐ 446 Americans w/Disabilities-Other	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN
◎ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi district Litigation ○ 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
Action under the False Claims Act, 31 U.S.C Section 3729

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A CLASS ACTION UNDER F R C P 23 **DEMAND $** _____ Check YES only if demanded in complaint
JURY DEMAND: YES ☒ NO ☐

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☒ If yes, please complete related case form

DATE June 14, 2011 **SIGNATURE OF ATTORNEY OF RECORD** _____

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The **JS-44** civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed Listed below are tips for completing the civil cover sheet These tips coincide with the Roman Numerals on the Cover Sheet

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence Use 11001 to indicate plaintiff is resident of Washington, D C , 88888 if plaintiff is resident of the United States but not of Washington, D C , and 99999 if plaintiff is outside the United States

III. CITIZENSHIP OF PRINCIPAL PARTIES This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II

IV. CASE ASSIGNMENT AND NATURE OF SUIT The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint You may select only one category You must also select one corresponding nature of suit found under the category of case

VI. CAUSE OF ACTION Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause

VIII. RELATED CASES, IF ANY If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form